UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

UNITED STATES EX REL,
SULEIMAN A. REFAEI
9520 West Avenue
Cincinnati, OH 45242

c/o Service to:
Carter Stewart
U.S. Attorney's Office
Southern District of Ohio
221 E. Fourth Street, Suite 400
Cincinnati, OH 45202

c/o Service to:
Eric H. Holder, Jr.
Attorney General for the United States
950 Pennsylvania Avenue NW
Washington, DC 20530-0001

Plaintiff-Relator

vs.

VANTAGE ONCOLOGY AND
ASSOCIATES, INC.
Valley Cancer Center
600 East First Street
Spring Valley, IL 61362

Also Serve:
Vantage Oncology and Associates, Inc.
1500 Rosecrans Avenue, Suite 400
Manhattan Beach, CA 90266

and

NEELIMA KABRE, M.D.
c/o Vantage Oncology and Associates, Inc.
Valley Cancer Center
600 East First Street
Spring Valley, IL 61362

Defendants

CIVIL ACTION NO: 1:10CV833

JUDGE: SPIEGEL, J.

[FILED IN CAMERA AND
UNDER SEAL]

COMPLAINT WITH JURY DEMAND

This is a *qui tam* action by Plaintiff-Relator Suleiman A. Refaei ("Relator") for himself, and on behalf of the United States, to recover damages and civil penalties arising from Defendants Vantage Oncology and Associates, Inc.'s ("Vantage") and Neelima Kabre, M.D.'s ("Kabre") actions in violating the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* ("FCA"). As set forth below, Defendants knowingly presented or caused to be presented thousands of false or fraudulent claims for payment or approval to federal health care programs and knowingly made used, or caused to be made or used false records or statements to get false or fraudulent claims paid or approved. Defendants consistently presented for payment charges associated with treatment for patients for services that were not necessary, not appropriately administered, improperly documented, improperly upcoded, and which were administered by non-licensed individuals. Executives at Vantage and Kabre had knowledge of these fraudulent billing practices. By knowingly and actively billing for services that were unnecessary, inappropriately administered or upcoded, Defendants submitted and caused to be submitted false claims to federal and state health care programs in violation of the FCA.

I. JURISDICTION AND VENUE

1. This action arises under the False Claims Act, 31 U.S.C. §§ 3729, *et seq.*

2. Jurisdiction over this action is vested in this Court by 31 U.S.C. § 3732(a), 31 U.S.C. § 3730(h), and 28 U.S.C. § 1331, in that this action arises under the laws of the United States.

3. Venue is proper in this district under 31 U.S.C. § 3732(a). The Defendant Vantage can be found, resides, and transacts business within the district.

II. THE PARTIES AND RELATED ENTITIES

4. Relator states that he is a resident of the State of Ohio. Relator was employed by Vantage from November 2008 through September 8, 2010 at which time Relator was terminated from his employment with Vantage. During the period of his employment Relator worked for Defendant Vantage as a Medical Physicist and performed his job duties in a capable and competent manner.

5. Defendant Vantage is a Delaware corporation incorporated in 2002 with its principal place of business in Manhattan Beach, California. Vantage provides a wide range of patient services including the use of diagnostic and therapeutic radiation treatment for radiation oncology through approximately thirty-four treatment centers located throughout the United States. These treatment centers are located in the following states: Arizona, California, Florida, Illinois, Indiana, Kentucky, Massachusetts, New York, Ohio, Pennsylvania, Rhode Island and Texas. While Relator was employed, his job duties were performed primarily at the Vantage Oncology Centers located in Streator, Illinois ("Streator") and at the Valley Cancer Center in Spring Valley, Illinois ("Spring Valley"). Relator has substantial first hand knowledge of the business activities at the Vantage Oncology Imperial Valley Cancer Center in El Centro, California, and South Suburban Cancer Center in Hazel Crest, Illinois. Vantage does business in the Southern District of Ohio at the Eastgate Commerce Center located at 4415 Aicholtz Road in Clermont County, Ohio.

6. Defendant Vantage offers a wide range of radiation oncologist services for those diagnosed with cancer. Radiation therapy involves the use of ionizing radiation to treat many forms of cancer. It can be delivered both internally and externally. The published goal of

radiation therapy is to give a cancerous tumor a lethal dose of radiation while limiting the exposure to the surrounding healthy tissue. When treating a patient with radiation, sophisticated dosage calculations are made in order to contour the shape and intensity of the radiation beam or the internal dose precisely to the targeted area.

7. Neelima D. Kabre, M.D. is a physician licensed to practice in the State of Illinois as a Radiation Oncologist. During the relevant period, she has been the Medical Director for both Streator and Spring Valley. She is also the Radiation Safety Officer ("RSO") for both Centers. As the RSO, she is statutorily responsible to create, implement and adopt policies and procedures designed to ensure compliance with all federal, state and industry regulations related to the use, handling, and disposal of radioactive materials and safe use of all generating equipment.

8. Defendant Vantage is a partner/affiliate with the Spring Valley and Streator Centers and with Neelima D. Kabre, M.D.

III. THE LAW

9. The FCA, 31 U.S.C. §§ 3729-33, provides for the award of treble damages and civil penalties for, inter alia, knowingly causing the submission of false or fraudulent claims for payment to the United States Government and for making or using false statements material to false or fraudulent claims paid by the United States. 31 U.S.C. §§ 3729(a)(1), (2); 31 U.S.C. §§ 3729(a)(1)(B) (May 2009).[1]

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[1] The FCA was recently amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 (FERA), enacted May 20, 2009. Although § 3729(a) was amended in its entirety, only § 3729(a)(2), which FERA renumbered as § 3729(a)(1)(B), can be applied retroactively back to and including June 7, 2008 by virtue of § 4(f) of FERA. "The amendments made by this section

10. The pre-FERA FCA provides, in pertinent part, that:

> "(a) Any person who (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government
>
> . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person . . . .
>
> (b) For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required."

31 U.S.C. § 3729.

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shall take effect on the date of enactment of the Act and shall apply to conduct on or after the date of enactment, except that (1) subparagraph (B) of section 3729(a)(1), as added by subsection (a)(1), shall take effect as if enacted on June 7, 2008, and apply to all claims under the False Claims Act (31 U.S.C. § 3729 *et seq.*) that are pending on or after that date. . . ." FERA, § 4(f). Because the conduct in this Complaint is alleged to have occurred from approximately 2002 through at least 2010, this Complaint will predominantly reference the pre-FERA numbering for paragraphs 3729(a) of the FCA with the limited exception of referencing the post-FERA numbering, pursuant to § 4(f), for conduct on or after June 7, 2008 when Defendants "knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim . . . ." 31 U.S.C. § 3729(a)(1)(B).

11. The post-FERA FCA was modified to reflect the below pertinent revisions:

> "(a) (1) any person who – (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim . . .
>
> . . .
>
> (b) For purposes of this section, (1) the terms "knowing" and "knowingly" – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud . . . ."

31 U.S.C. § 3729 (May 2009).

12. The standard of proof under the FCA is preponderance of the evidence. 31 U.S.C. § 3731(c).

IV. THE FEDERAL HEALTH CARE PROGRAMS

A. Medicare Part B

13. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services and items. 42 U.S.C. §§ 1395 *et seq*. Health and Human Services ("HHS") is responsible for the administration and supervision of the Medicare program. Centers for Medicare and Medicaid Services ("CMS") is an agency of HHS and directly administers the Medicare program. The Medicare program has several parts, including Medicare Part B ("Supplementary Medical Insurance for Aged and Disabled"). 42 U.S.C. § 1395k; 42 C.F.R. § 410.10.

14. The Medicare Part B program is a 100% federally subsidized health insurance system for eligible persons aged 65 and older and persons with qualifying disabilities, who may enroll in the program to obtain benefits in return for payments of monthly premiums as

established by HHS. The benefits covered by the Medicare Part B program include medical treatment and services by physicians under 42 U.S.C. § 1395k(a)(2)(B) in Illinois, and the other contractors responsible for servicing the Vantage centers in other locations within the United States.

15. The United States provides reimbursement for Medicare claims from the Medicare Trust Fund through CMS. To assist in the administration of Part B of the Medicare program, CMS contracts with "carriers." 42 U.S.C. §1395u. Carriers, typically insurance companies, are responsible for processing the payment of Part B claims to providers on behalf of CMS. *Id.* Wisconsin Physician Service ("WPS") is the carrier responsible for processing the payment of Part B claims to Vantage on behalf of CMS in the State of Illinois. Other carriers are responsible for the processing of payments for the other radiation centers operated by Vantage outside the State of Illinois.

16. At all relevant times herein, Vantage knowingly submitted and caused false claims to be submitted to Medicare through its contractor, WPS.

B. The Medicare Provider Agreement

17. Illinois medical providers claim Medicare Part B reimbursement from WPS pursuant to written provider agreements. WPS receives, processes, and pays or rejects those claims according to Medicare rules, regulations and procedures.

18. Vantage and Kabre signed or caused to be executed provider agreements with Medicare that permitted Vantage to submit claims and accept payment for services provided by Kabre and Vantage physicians for Medicare patients.

19. Medicare assigns each participating provider a unique billing Provider

Identification Number ("PIN"). Vantage submits its Medicare claims via its PIN which it uses at its various treatment centers. Vantage and Kabre submitted enrollment forms identified as CMS-855B and CMS-855I respectively in order to participate in the Medicare plan and to lawfully be permitted to submit claims for charges incurred as a result of treating individuals covered by Medicare. Submission of these enrollment forms permitted both Vantage and Kabre to electronically submit CMS-1500 forms to its carrier, WPS.

20. In order to participate in the Medicare program, Vantage, at its Streator, Spring Valley and all other locations, was required to complete and submit to CMS its enrollment application: CMS-855I. That enrollment application provided:

> "Section 14: Penalties for Falsifying Information
>
> 1. 1.18 U.S.C. § 1001 authorizes criminal penalties against an individual who, in any matter within the jurisdiction of any department or agency of the United States, knowingly and willfully falsifies, conceals or covers up by any trick, scheme or device a material fact, or makes any false, fictitious, or fraudulent statements or representations, or makes any false writing or document knowing the same to contain any false, fictitious or fraudulent statement or entry. . . .
>
> 2. Section 1128B(a)(1) of the Social Security Act authorizes criminal penalties against any individual who, "knowingly and willfully," makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program. . . .
>
> 3. The Civil False Claims Act, 31 U.S.C. § 3729, imposes civil liability, in part, on any person who:

a) knowingly presents, or causes to be presented, to an officer or any employee of the United States Government a false or fraudulent claim for payment or approval;

b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; or

c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

The Act imposes a civil penalty of $5,000 to $10,000 per violation, plus three times the amount of damages sustained by the Government.

4. Section 1128A(a)(1) of the Social Security Act imposes civil liability, in part, on any person (including an organization, agency or other entity) that knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency...a claim...that the Secretary determines is for a medical or other item or service that the person knows or should know:

a) was not provided as claimed; and/or

b) the claim is false or fraudulent. . . .[2]

5. 18 U.S.C. 1035 authorizes criminal penalties against individuals in any matter involving a health care benefit program who knowingly and willfully falsifies, conceals or covers up by any trick, scheme, or device a material fact; or makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false fictitious, or fraudulent statement or entry, in connection with the delivery of or payment for health care benefits, items or services. . . .

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[2] 18 U.S.C. § 1128(a)(1)(E) prohibits any person from presenting a claim for medical services that a person knows or should know is not medically necessary.

6. 18 U.S.C. 1347 authorizes criminal penalties against individuals who knowing and willfully execute, or attempt, to execute a scheme or artifice to defraud any health care benefit program, or to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by or under the control of any health care benefit program in connection with the delivery of or payment for health care benefits, items, or services. . ."

21. In light of the foregoing penalties, Vantage, at its Streator, Spring Valley and all other Vantage locations, certified to CMS:

"Certification Statement

You MUST sign and date the certification statement below in order to be enrolled in the Medicare program. In doing so, you are attesting to meeting and maintaining the Medicare requirements stated below.

. . .

3. I have read and understand the Penalties for Falsifying Information, as printed in this application. I understand that any deliberate omission, misrepresentation, or falsification of any information contained in this application or contained in any communication supplying information to Medicare, or any deliberate alteration of any text on this application form, may be punished by criminal, civil, or administrative penalties including, but not limited to, the denial or revocation of Medicare billing privileges, and/or the imposition of fines, civil damages, and/or imprisonment.

4. I agree to abide by the Medicare laws, regulations and program instructions that apply to me or to the organization listed in Section 4A of this application. The Medicare laws, regulations, and program instructions are available through the fee-for-service contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable

conditions of participation in Medicare.

. . .

8. I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

22. Dr. Kabre executed a CMS-855B Medicare Enrollment Application. That application provided the same language as a penalty for falsifying information as that is identified in the CMS-855I for Vantage. The CMS-855B contained the same certifications as the CMS-855I.

23. Vantage and a physician who treats a Medicare patient is required to submit an electronic or hard-copy Medicare Health Insurance Claim Form ("HCFA form 1500") to the carrier, who on behalf of CMS, pays a portion of the claim. In submitting Medicare claim forms, providers must certify that the information included on the form presents an accurate description of the services rendered and that the services were medically necessary.

24. In particular, Vantage and Kabre certified to the following language on the CMS-1500 enrollment form that they submitted to Medicare: "I certify that the services shown on this form were medically indicated and necessary for the health of the patient . . . ."

"NOTICE: This is to certify that the foregoing information is true, accurate and complete. I understand that payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of a material fact, may be prosecuted under applicable Federal or State laws."

25. By participating in the hard copy and computerized billing of Medicare claims,

Vantage physicians agreed to submit claims using HCFA form 1500 and were aware of the required certifications.

C. The TRICARE Program

26. TRICARE, formerly known as CHAMPUS, is a federal health benefits program, established by 10 U.S.C. §§ 1071-1110, that offers a triple option benefit plan: an HMO option; a PPO option; and a fee for service option. TRICARE/CHAMPUS is administered by the Secretary of Defense. TRICARE/CHAMPUS provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

27. The regulatory authority establishing the TRICARE/CHAMPUS program provides reimbursement to individual health care providers applying the same reimbursement scheme and coding parameters that the Medicare program applies. 10 U.S.C. §§ 10790)(2)(institutional providers), (h)(1)(individual health care professional)(citing 42 U.S.C. 1395, *et seq.*). Services and supplies that are not medically or psychologically necessary for the diagnosis or treatment of a covered illness or injury are specifically excluded from coverage. 32 C.F.R. § 199.4(8)(1).

28. TRICARE/CHAMPUS prohibits improper billing practices such as unbundling, fragmenting, code gaming, and duplicate billing as a means of manipulating CPT codes to increase reimbursement. 32 C.F.R. §§ 199.9(c). Such practices are considered fraudulent and abusive and a misrepresentation of services. 32 C.F.R. §§ 199.9(c)(5) - (c)(8).

D. Medicaid Program

29. Medicaid is a joint federal-state program that provides health coverage or nursing home coverage to certain categories of care assisted individuals. 42 U.S.C. § 1396-1. Congress

and CMS set out general rules under which Medicaid operates. Each state runs its own program. Medicaid is partially funded by federal funds and partially funded by state funds. 42 U.S.C. § 1396(a). Eligibility for Medicaid is largely determined by income. Each state must operate its own Medicaid system, but that system must conform to federal guidelines in order for the state to receive matching funds and grants. In Illinois the Medicaid system is administered by the Department of Heath Care and Family Services ("HFS").

E. Medical Coding

30. The American Medical Association assigns and publishes numeric codes, known as Current Procedural Terminology (CPT) and Health Care Financing Administration Procedure Coding System (HCPCS). The codes are a systematic listing of procedures and services performed by health care providers. They include codes for radiation oncology and related services, based on complexity, supervision, and documentation requirements. Health care providers use CPT and HCPCS codes to describe and evaluate the services for which health care providers claim payment. Healthcare benefit programs use these same codes to decide whether to issue or deny payment. Each healthcare benefit program establishes a fee reimbursement for each procedure described by a CPT or HCPCS code.

31. Each year Medicare publishes a Physician's Fee Schedule in which all of the CPT codes are listed together with the reimbursement Medicare allows for each code. Medicare lists the amount of reimbursement paid in the facility setting (i.e., hospital) and the non-facility setting (i.e., office).

32. As a condition of participation in the Medicare Part B program, providers agree to be familiar with, and abide by, the program's reimbursement policies. In particular, Vantage

certified to the following requirements when it applied for Medicare enrollment:

> "(3) I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.
>
> (5) I agree that any existing or future overpayment made to the supplier by the Medicare program may be recouped by Medicare through the withholding of future payments.
>
> (6) I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity."

33. Vantage, its employees, and Dr. Kabre had a duty to be knowledgeable of the statutes, regulations, and guidelines regarding coverage for Medicare services, which include the policies relevant to radiation oncology and related services.

34. Vantage employees and physicians, including Dr. Kabre, certified that they were knowledgeable of Medicare's requirements in provider enrollment forms submitted.

35. Medicare covers, and participating providers agree to submit, claims only for services that are medically necessary to diagnose and treat illness or injury, and for which the provider maintains adequate supporting documentation, such as physician's orders, medical necessity notes, and other pertinent documentation justifying the treatment administered. 42 U.S.C. § 1395y(a)(1)(A). A physician may not be reimbursed by Medicare for unreasonable or

medically unnecessary services.

36. Absent certain exceptions, Medicare Part B does not cover, and providers agree not to submit, claims for services provided that are not necessary, not appropriately administered, or not properly documented.

37. In order for Defendants to be properly reimbursed for patient care by the Medicare program, TRICARE or Medicaid, CMS requires that the treating physician order the applicable services, appropriately administer those services, appropriately document the justification and administration of those services, submit only those codes that correlate with the notes made by the physician in the medical record, and adhere to coding guidelines when assigning applicable codes.

V. VANTAGE'S RADIATION TREATMENT MODALITIES

38. Radiation therapy uses high-energy radiation to kill cancer cells by damaging the DNA in cancer cells so that they cannot repair or reproduce. Patients can receive radiation therapy in two ways, either externally or internally. Internal radiation is referred to in the industry as brachytherapy. Radiation therapy is less invasive than other cancer treatments making it an attractive option for men and women who want to maintain their lifestyles and jobs while receiving treatments. When a physician determines that radiation therapy may be a treatment option for his or her patient, a referral is made to a radiation oncologist. Oncologists at Vantage are the beneficiaries of these physician referrals.

39. Vantage utilizes radiation therapy in a series of different modalities. During external beam radiation, a beam of radiation is directed to the tumor and immediate surrounding area in order to destroy the tumor and any nearby cancer cells. Internal radiation or brachytherapy is the placement of radioactive sources in or next to a tumor. Because the radiation sources are

placed so close to the tumor, doctors can deliver a large dose of radiation directly to the cancer cells with minimal exposure to the normal tissue.

40. At Vantage, patients can be administered several different types of radiation treatment depending on the complexity and location of the tumor. Treatment plans require a detailed evaluation of the tumor and the patient's anatomy. As such, the CPT codes affiliated with radiation oncology require detailed documentation and specific physician supervision.

41. One method of treatment used by Vantage in administering radiation therapy is identified as Image Guided Radiation Therapy ("IGRT"). IGRT is used externally by Vantage to help accurately deliver radiation therapy in the treatments of cancer. The use of repeat imaging during the course of the radiation treatment is to enhance accuracy and the precision of the radiation delivery. The physician can image the target before or during the delivery of radiation treatment while the patient is laying on the treatment table. These images will be compared with original simulation images. IGRT involves conformal radiation treatment guided by imaging such as CT, x-ray or ultrasound taken in a treatment room before or during treatments. It is commonly used with Intensity Modulated Radiation Therapy ("IMRT").

42. A second modality utilized by Vantage and its radiation oncologists is IMRT. IMRT involves the use of multiple high-energy external x-ray beams to target the tumor. The radiation beams are calculated in advance as part of a patient specific treatment plan to deliver precise radiation while minimizing the dose to the normal surrounding tissues. The strength of the beams can be adjusted as necessary depending on the size, location and stage of the cancer. IMRT is a more complicated treatment than normal external treatment. Before planning the treatment to be utilized for a patient, a physical examination and medical history review must be

conducted. This treatment requires direct supervision by a radiation oncologist in order to obtain payment from CMS.

43. A third treatment involves seed implants (Low Dose Rate Brachytherapy). Seed Implant Brachytherapy involves the use of tiny radioactive isotopes called "seeds" that are permanently placed in the body. This form of treatment controls the dose and reduces exposure to the normal healthy tissues that surround the tumor. The relative amount of radiation is very low and over a period of time, implanted seeds lose their radioactivity and can remain in the body. In the early stages of prostate cancer for example, seed implantation is often used as a stand alone treatment. A prostate seed implant may be utilized unilaterally for treatment or as additional treatment in conjunction with moderate doses of external beam irradiation. The prostate seed implant procedure is a multi-step process that is typically completed primarily by a radiation oncologist with the assistance of urologist.

44. It is essential that postimplant dosimetry be performed on all patients undergoing permanent prostate brachytherapy. Dosimetry is the calculation of the absorbed dose in tissue resulting from the exposure to ionizing radiation seeds. The dose distributions following implantation are never exactly the same for each person as those planned prior to the implant. Because the dose distributions may differ ever so slightly, it is important to document the actual dose that the prostate and normal adjacent tissues will receive over the life of the implant. This can only be determined if a postimplant dosimetric assessment is performed.

45. Either x-rays or CT simulation films followed by 3D simulation and reconstruction are obtained following implantation (about 30 days post implant) to verify that the final seed array meets that specified in the treatment plan. The final seed array is then subject to computer

brachytherapy isodose calculations to ensure that the prostate receives the desired dose radiation.

46. The information obtained from postimplant dosimetry is essential for optimal patient care. Significant over-dosing of the prostate may increase the risk of side-effects. Significant under-dosing of the prostrate can lead to treatment failure. Therefore, the federal government has determined that any results which demonstrate a variation of 20 percent of the proposed coverage area versus the actual area in the implantation of the radioactive seeds is an immediate reportable medical event to the Nuclear Regulatory Commission ("NRC") that a provider must make within 24 hours of discovery of the failed treatment.

47. At the conclusion of the course of treatment, a written summary of the treatment delivery parameters is generated, including the total dose of brachytherapy and the total dose of external beam therapy, if it is given, treatment technique, treatment volume, acute side effects, clinical course, and patient disposition. Patients treated with brachytherapy must be evaluated after treatment at regular intervals by the radiation oncologist for response and early and late effects on normal tissues by the radiation.

VI. VANTAGE'S FRAUDULENT ACTIVITIES

48. As a medical physicist, Relator was working mainly at the Spring Valley and Streator Centers. Relator has first hand knowledge of the fraudulent practices by Defendants at these locations. Relator became familiar with the operations and practices of other Vantage Centers through temporary coverage by him at these locations, through orientation, and by talking to co-employees and staff members located at the other Vantage Centers. Accordingly, Relator has direct knowledge of the practices at Spring Valley and Streator, along with the Centers located at South Suburban Cancer Center, Hazel Crest, Illinois; Imperial Valley Cancer Center, El

Centro, California; Riverside Radiation Therapy Center, Riverside, California; St. Bernardine Radiation Therapy Center, San Bernardino, California; Redhawk Radiation Therapy Center, Temecula, Brooklyn; Radiation Oncology; Northern Boulevard Radiation Oncology, New York; and Evansville Cancer Center, Indiana.

49. From prior to November 2008 through at least September 2010, Defendants have defrauded the United States by knowingly submitting and knowingly causing false or fraudulent claims for improper and unjustifiable radiation oncology services to be submitted to federal health care programs and state Medicaid programs.

50. These unlawful activities by the Defendants damaged the United States and the State of Illinois and other state Medicaid programs by causing them to pay more to Defendants than the amounts to which they were actually entitled.

51. Defendants routinely billed for services without providing the necessary supervision, without rendering the service for which the United States was billed, without including the necessary documentation to support the code, and for services that were inappropriately administered.

52. The federal health care programs, the State of Illinois and other applicable states paid millions of dollars to Defendants that should not have been paid.

53. Despite the relevant CPT codes' explicit parameters that Defendants must follow in billing for procedures they performed, Defendants knowingly failed to administer the services properly in violation of Medicare guidelines for the specific purpose of increasing their billings and revenue.

A. Defendants' Submission For Payment Relating To Patients Who Received Improper Doses Of Radiation.

54. During the course of Relator's employment, Relator became aware of numerous occasions where Defendants billed Medicare and Medicaid for radiation services provided to patients that were inappropriately administered.

55. The regulations set forth under 10 C.F.R. 35.3045 provide that Vantage is required to report to the NRC treatment to a patient that triggers a medical event. Specifically, 10 C.F.R. 35.3045(a) mandatorily requires Vantage:

> "(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in--
>
> (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
>
> (i) The total dose delivered differs from the prescribed dose by 20 percent or more;
>
> (ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
>
> (iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more."

56. During the year 2008 and thereafter, patients regularly received inappropriate doses of radiation that were administered by Vantage and/or Dr. Kabre for patients undergoing brachytherapy that differed from the prescribed doses of radiation for each patient.[3] Upon

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[3] Relator believes this failure to follow federal law in refusing to report brachytherapy negative medical events has been going on since 2002.

discovery of the administration of the inappropriate doses, Vantage was required to report this event to the NRC. The report as required under 10 C.F.R. 35.3045(c) and (d) was to be made to the NRC Operations Center the following calendar day after discovery of the medical event, and thereafter a written report submitted to the NRC Regional Office within 15 days after the discovery of a medical event.

57. The patients who received the federally prohibited doses have been identified, but are not listed in the complaint in order to protect their privacy. During the year 2008 they number at least 19 patients at Streator and Spring Valley. The discovery of the prohibited doses for these patients occurred during the post implant dosimetric assessment.[4] The identity of these 2008 patients and the dates of the dosimetric treatment identifying a variation of at least 20 percent between the pre-implantation prescription for radiation dosage seeds and the post-implant dosimetric assessment in violation of the federal regulations will be revealed once appropriate precautions are taken under HIPPA.

58. Vantage and Kabre knowingly billed the United States for these services even though the patient was inappropriately treated. The CPT codes associated with these procedures under evaluation and planning are: 77470, 77328, 77300, 77331 (technical billing); 9924x, 77263, 77470, 76873, 77328, 77300, 77331 (professional billing); and 9924x, 77263, 77470, 76873, 77328, 77300, 77331 (global billing). The CPT codes associated with these procedures

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[4] Most recently the NRC fined the VA Medical Hospital in Philadelphia almost $227,500 for 8 violations of NRC requirements in failing to report a radiological medical events that resulted in nearly 100 medical errors. The history and findings of the NRC can be accessed at www.NRC.gov/reading-rm/doc. The identification of the activities at Vantage in failing to adhere to the applicable regulatory guidelines is much worse and far greater in terms of number of reportable events then that which occurred in Philadelphia.

under application are: 76000, 77332, 77778, 77790, 77370, C1718, C1720, C1728, C1715 (technical billing); 55859, 76965, 76000, 77332, 77778, 77790 (professional billing); and 55859, 76965, 76000, 77332, 77778, 77790, 77370, Q3001, 99070 (global billing). The CPT codes associated with these procedures under post implant are: 76370, 77295, 77336 (technical billing); 77295 (professional billing); and 76370, 77295, 77336 (global billing). The CPT codes associated with these procedures under standard brachytherapy are: 77290, 77328, 77336 (technical billing); 77290, 77263 (professional billing); and 77290, 77328, 77336 (global billing).

59. In addition to the foregoing patients, in December 2008, Patient X was implanted with almost 170 percent of the prescribed dose of radiation. This dose was to be followed up with external beam radiation of an additional 50 percent of the prescribed dose. Thus, this patient received 1.7 times the prescribed dose of radiation. This inappropriate treatment also violated the NRC regulations and was not medically necessary under CMS rules and regulations, and therefore was not reimburseable.

60. With respect to Patient X, Relator forwarded by electronic mail this reportable medical event on December 12, 2008 to the Vantage administration, including Dr. Kabre and Dr. Aissi, who at the time was the Vice President of Medical Physics for Vantage. A copy of an email corroborating this report is attached hereto and incorporated as Exhibit "A". Vantage and Dr. Kabre chose to purposely cover up and not report this incident to the NRC and instead billed for the treatment under Dr. Kabre's pin number.

61. These are not the only patients who received an inappropriate dosage of seed radiation through brachytherapy. Significant numbers of patients throughout the Vantage system have also received inappropriate doses of radiation each of which constitute a medical event

which has not been reported to the NRC. Vantage agreed in the presentation of its claims for payment to CMS to refrain from knowingly billing the United States for inappropriate treatment or treatment that is medically unnecessary. Knowingly submitting bills to CMS which are fictitious, materially false or fraudulent in the connection to or delivery of, or payment for healthcare services constitutes a false claim for which the United States is entitled to damages.

62. In 2009 the Defendants actively engaged in altering the records so that the inappropriate doses of seed radiation to their patients would not be reflected in the medical record for the patient, and the medical records for those patients would not reflect that a medical event did occur. Therefore those medical events were not reported to the NRC. When the patients' medical records showed the actual reportable event because of inappropriate treatment, a second set of records for each patient was changed by having Dr. Kabre at a later date dictate notes to reflect the change in results. In short, Defendants maintained two sets of medical records for numerous patients. The patients for whom the results of the radiation treatment were changed are known, but have not been included in order to protect their privacy.

63. Dr. Kabre and Vantage upper management, including Dr. Aissi, discussed the seed implant violations on numerous occasions. In late 2009 Kabre sent numerous patient records to Dr. Aissi for review and input. On October 21, 2009, Relator offered to have an independent peer review of the records. A copy of the email corroborating this request is attached hereto as Exhibit "B" and incorporated by reference. Subsequent to receiving the email, Dr. Kabre telephoned Relator on two to three occasions verbally reprimanding him for requesting the peer review in writing.

64. Subsequent to the Defendants' treatment of the patients who received

inappropriate doses of radiation, the Defendants knowingly submitted electronic claims to WPS for payment from the United States and CMS relating to the treatment of these patients while representing that these patients had been appropriately treated when in fact they had not.

65. The claims for payment were knowingly false because the services provided on which the claims were based were not appropriately administered and/or were improperly documented and/or were fraudulently submitted in violation of the FCA.

B. Defendants Failed To Supervise Radiation Treatment And Patient Care For IGRT Radiation Treatment.

66. The administration of radiation therapy requires specific supervision. Failure to render that supervisory care makes such services non-reimburseable by CMS because they are medically unnecessary. 42 C.F.R. § 411.15(k)(1).

67. Defendants systematically administered an Image Guided Radiation Therapy or IGRT procedure to its patients without the required level of physician supervision.

68. 42 C.F.R. § 410.32(b) sets forth the requirement that diagnostic tests are not reasonable and necessary, and hence are not payable, unless they are performed under the appropriate level of supervision by a physician. Specifically, that provision provides:

> "(b) Diagnostic x-ray and other diagnostic tests -- (I) Basic rule. Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act [42 U.S.C. § 1395x(r)]. Services furnished without the required level of supervision are not reasonable and necessary (see § 411.15(k) (I) of this chapter)." (Emphasis added).

42 C.F.R. § 410.32(b)(3) sets forth three different levels of physician supervision, general, direct,

and personal, and they are defined as follows:

> "(i) General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.
>
> (ii) Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.
>
> (iii) Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

69. IGRT allows physicians to more precisely target the delivery of radiation to affected areas and it only became eligible for Medicare reimbursement in 2006. At the time these services were rendered, the CPT code for IGRT, CPT 77421, required personal supervision, which means the "physician must be in attendance in the room during the performance of the procedure." 42 C.F.R. § 410.32(b)(3)(iii). Prior to January 1, 2009, all IGRT tests were required to be performed under the personal supervision of a physician, and subsequent to January 1, 2009, the tests were to be performed under a physician's direct supervision.

70. In utilizing IGRT, a patient is placed on the treatment unit where he is subjected to imaging procedures such as CTs, KV or MV x-rays. These tests are performed in a treatment room just prior to the patient receiving his or her daily radiation therapy treatment. After the images are reviewed, the patient's position is adjusted as necessary to allow for the precise delivery of radiation to the tumor while minimizing the amount of radiation delivered to adjacent

body areas. Prior to January 1, 2009, the images were to be reviewed by a physician before the delivery of the radiation to the tumor.

71. Relator has first hand knowledge of Vantage's practices with respect to the IGRT procedures performed at Spring Valley and Streator. On any given day, approximately 20 IGRT procedures were performed at these two Centers. Most of these treatments were billed to Medicare or Medicaid. The approximate number of daily IGRT procedures performed at all Vantage locations exceeds 400.

72. While using the CPT Code 77421 and prior to January 1, 2009, Vantage rarely had a physician present in the treatment room during an IGRT procedure. Subsequent to January 1, 2009, it was rare for a physician to be in the same building while the procedure was being performed. In fact, it was rare for a physician to be present at the Streator address on a Wednesday while the IGRT's were being performed at that location during that day of the week. This lack of supervision existed throughout the Vantage radiation centers, including but not limited to the Vantage center in El Centro, California wherein Dr. Farah Ramez was the medical oncologist responsible for ensuring that appropriate supervision for the radiological procedures occurred.

73. To create the illusion that radiology oncologists were providing real time supervision, Vantage used third-party remote party access software. The software through the internet gotomypc.com does not satisfy the explicit requirement of being in the room where the procedure is administered or even in the same office. The system, as designed, did not allow for physician supervision prior to the administration of treatment.

74. Vantage normally had the IGRT procedures performed by radiation therapists with

no real time involvement from a radiation oncologist. For example, the therapist after taking the x-ray images in the treatment area would write on a sheet that they performed the x-ray. Rarely did the oncologist attend or review the images. On most occasions it was a common practice that the radiation oncologist signed the IGRT sheet once or twice a week without reviewing the images prior to treatment. The therapist would fill out an information sheet on a tabulated form and then check the tabs or line on the document to confirm the therapist's activities.

75. CMS requires specific documentation in the patient's record corroborating the administration of the appropriate physician supervision on the day of the treatment. Services that are not performed under the appropriate supervision are not considered reasonable and necessary and therefore are not covered under Medicare. 42 C.F.R. 410.32 (b); 42 C.F.R. 410.32(d)(2).

76. Invariably, the therapist would proceed with the radiation treatment for the patient without the physician having reviewed the prior set of images, being available in the room, or in the same building location. The images obtained using the IGRT procedure would be reviewed by the radiation oncologist only after the treatment was completed or not at all. Frequently the radiation oncologist would be unavailable and not present in the building while the procedure was being performed. On these occasions the treatment records would be signed days later by the physician oncologist including Dr. Kabre.

77. For example, Dr. Kabre was on vacation from December 1, 2008 through at least December 23, 2008, and from November 2009 through December 2009. During this period of time Vantage submitted bills for services to the United States relating to Code 77421 for Dr. Kabre while Dr. Kabre was out of the country or on vacation. Therefore, she could not have provided the appropriate supervision for the patients for which IGRT procedures were performed.

78. Relator regularly reviewed patient's charts weekly and bi-weekly and rarely was the IGRT certification completed with the appropriate supervision while the procedure was being performed by the therapist or on the day the services were rendered.

79. The failure to provide appropriate physician supervision to patients undergoing IGRT's is memorialized on numerous compliance alerts and compliance review summaries conducted by Vantage on an in-house basis. For example, in a memorandum dated February 24, 2009 from Nicki Valero, she noted in a sample of patient files numerous deficiencies relating to the Vantage billing to CMS. (Attached as Exhibit "C" hereto and incorporated by reference). For example, Valero noted:

> "5. IGRT must be charged out using the name of the physician who was in the office supervising and signing off of the shift/image. Virtual review outside the office where the service was performed does not meet the supervision requirements of IGRT." (Emphasis added).[5]

On February 10, 2009, Vantage identified the problem with billing IGRT under Code 77421 when physicians were not in the office. Specifically, the compliance department found 17 separate problems in a sample of just 12 patient charts at the Spring Valley center. One of the issues raised by the compliance department also related to the IGRT supervision requirements:

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[5] Under the IGRT Guidelines attached as Exhibit "C", the compliance office reminded Vantage personnel that CPT code 77421 requires the physician to sign the patient records and documents daily to bill the code. If the doctor does not sign the daily/shift image, Vantage may not charge for the technical or the professional component associated with this procedure. (Exhibit "C", IGRT Guideline).

"11. X-ray based IGRT 77421 must be billed globally or not at all. Doctor must sign off on the shift/image daily for the code to be charged. The Shift Sheet demonstrates the physician only signed off weekly. The technical component of 77421 has a supervision level "3" meaning in direct attendance and the documentation must support this level of supervision.
Corrective Action
- Review supervision and documentation requirements for 77421" (Emphasis added).

(Attached as Exhibits "C" and "D" herein). The foregoing is only a sample of the compliance deficiencies identified by Vantage's compliance officer detailing the submission of bills while failing to properly supervise and/or document the necessity of IMRT radiation therapy.

80. Defendants' failure to supervise the administration of IGRT despite knowledge of their non-compliance resulted in the knowing submission of millions of dollars of false claims to federal and state health care programs for payment relating to claims that were medically unnecessary under 42 C.F.R. § 410.32(b)(3) and 42 C.F.R. § 411.15(k)(1).[6]

C. Defendants Administered Intensity Modulated Radiation Therapy (IMRT) And Submitted False Claims For These Tests. (CPT Codes 77301 And 77418).

81. IMRT differs from conventional therapy in that it shapes radiation beams to closely approximate the size of the tumor being treated. The intensity of the radiation in IMRT can be changed during treatment to spare damage to the adjoining normal tissue than that which occurs during conventional radiation therapy. Accordingly, the professional and

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[6] The failure to document the necessity for a procedure and subsequently billing Medicare is also apparent during the performance of the prostate seed implant procedure wherein Ms. Valero writes: "No procedure note in file to support prostate seed implant charges 77778 and 77790." (Exhibit "D", #16). These are not reimburseable under Medicare.

technical billing of IMRT requires direct supervision — "the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure." See 42 C.F.R. § 410.32(b)(3)(ii). Where direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test. 42 C.F.R. § 410.32(b)(3).

82. IMRT is therefore indicated in situations in which extremely high precision is required.

83. Where such high precision is not required, conventional radiation therapy may achieve the same or better results at significantly lower cost. IMRT is billed using various CPT codes, including 77301 and 77418.

84. On numerous occasions the Relator and Vantage's own compliance department advised Vantage and its physician employees, including Dr. Kabre, that submissions of bills relating to services performed for IMRT's were not in compliance with Medicare supervision requirements. Nevertheless, Vantage and Kabre submitted bills to IMRT providers without being present in the office and immediately available to furnish assistance and direction throughout the performance of the procedures.

85 Because IMRT is significantly more expensive than conventional radiation therapy, physicians have a financial incentive to utilize IMRT in situations where other treatment methods may achieve the same or better results. Consequently, Medicare has placed limits on when IMRT may be used, and has required those physicians to document in the patient's medical record the reasons why IMRT is necessary.

86. Vantage was aware of these provisions in part due to the requirement that it must

follow the Local Coverage Decision ("LCD") issued by WPS and applicable to Vantage when submitting bills for charges incurred by patients to CMS. (Attached as Exhibit "E").[7] The LCD dictates that IMRT is not a replacement therapy for conventional and 3D conformal radiation therapy methods. Vantage was also aware of the guidelines as set forth in its compliance report of February 24, 2009. (Exhibit "C", "IGRT Guidelines").

87. According to the LCD, IMRT is only considered reasonable and necessary in instances where sparing the surrounding normal tissue is of added benefit and at least one of the following conditions is met:

- The target volume is in close proximity to critical structures that must be protected.
- The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures.
- An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision.
- The target volume is concave or convex, and critical normal tissues are within or around that convexity or concavity.
- Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment.

88. Additionally, according to the LCD and CMS a physician that utilizes IMRT radiation therapy must document the indications for IMRT and consider the specific criteria in the

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[7] The LCD attached is the most recent issued by WPS. The standards identified in this version are virtually if not the same as earlier versions.

documentation which provides the basis to use and charge for this therapy.

89. Accordingly, in order to be reimbursed for charges relating to IMRT radiation therapy, not only must Vantage adhere to the proper level of supervision, but the medical record for the specific patient in which IMRT radiation therapy is utilized must include:

a. the reasonable and necessary requirements as outlined under the coverage and limitations sections of the LCD,

b. a defined set of goals and requirements of the treatment plan,

c. a statement by the treating physician documenting the special need for performing IMRT on the patient in question,

d. a signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV),

e. the target verification methodology which must include the following:

i. documentation of the clinical treatment volume (CTV) and the planning target volume (PTV),

ii. documentation of immobilization and patient positioning,

iii. means of dose verification and secondary means of verification,

iv. independent basic dose calculations of monitor units have been performed for each beam before the patient's first treatment,

f. documentation of fluence distributions (re-computed and measured in a phantom or dosimetry measuring device) is required, and

g. identification of structures that traverse high-and-low-dose regions created by respiration is indicated. Voluntary breath-holding alone is not a satisfactory solution for

accounting for organ motion. (Exhibit "C") (Exhibit "F").

90. Vantage and its oncologists, including Dr. Kabre, are members of the leading oncology society, the American Society for Therapeutic Radiology and Oncology ("ASTRO"). ASTRO continually identified for its members the inherent danger of upcoding billing for IMRT's without the necessary medical documentation backup.

91. For many years, Vantage and Dr. Kabre have systematically overused IMRT rather than the alternative/conventional radiation therapy in a significant number of its patients regardless of medical necessity. Vantage and its oncologists also failed to provide the direct level of supervision that is required and have routinely failed to document the medical necessity of IMRT usage. Relator has in his possession the names of the patients at Streator and Spring Valley who received IMRT's and IGRT's, but has not identified those herein in order to protect their privacy. Written evidence of the inappropriate and over-utilization of IMRT has been recognized by Vantage in its internal audits. Specially, on February 10, 2009, Ms. Valero, the Compliance Director, noted the deficiency at the Spring Valley and Streator locations. She stated:

> "9. IMRT note of medical necessity needs to specify the critical structures or reason why IMRT was best method for that particular patient compared to 3D per Medicare LCD.
> Corrective Action
> • Review Medicare IMRT policy documentation requirements
>
> 10. Missing documentation of delivery to a phantom for QA of the IMRT plan.
> Corrective Action
> • Review Medicare IMRT policy documentation requirements

. . .

12. IMRT plans must have an independent MU calc for each beam before the plan is used to treat the patient. If you create an IMRT boost plan you must have documented MU calcs for each of the boost ports to charge the calcs 77300. Patient [name redacted] has the phantom QA for the initial and boost but only independent MU calcs for the initial IMRT plan.
Corrective Action
- Review Medicare IMRT policy documentation requirements

13. Physics consultation performed for QA or verification of the IMRT plan is not allowed as this work is included in the IMRT plan code 77301. Physics consultation may be performed with IMRT if request from physician is clearly documented and for a reason other than QA or verification of the IMRT plan.
Corrective Action
- Review ASTRO clarification of what is included in IMRT plan code 77301"

(Attached hereto as Exhibit "D" and incorporated by reference). This compliance report is just one of many reports issued by Vantage which highlights Vantage's failure to comply with applicable billing and submission requirements under Medicare thereby rendering the bills and services medically unnecessary and therefore not reimburseable.

92. Most recently, in August 2010, a patient being administered radiation at Streator pursuant to one of the aforementioned procedures died on the Vantage premises. A physician was unavailable at that time to assist in the resuscitation as required under federal law in order to bill for that radiology service.

93. By knowingly submitting claims under CPT codes 77301 and 77418 to the fiscal intermediary and CMS that are false, the Defendants' actions constitute a violation of the FCA.

Millions of dollars have been paid by CMS and Vantage for IMRT's that were either not supervised, inappropriately provided, or not appropriately documented and therefore upcoded.

D. Vantage's Improper Billing Requests Under CPT Code 77470 - - "Special Treatment Procedure".

94. In certain cases, physicians performing radiation therapy are required to expend additional work and effort beyond what would normally be expected for a certain procedure. Under those circumstances, the physician may obtain additional payment by billing CPT code 77470 - "Special Treatment Procedure."

95. The use of code 77470 is intended to be the exception, and it is improper to routinely use the code without specific case-by-case justification. There is no case in which it is routinely used, and therefore, the physician should decide to report CPT code 77470 on a case-by-case basis and document the work effort involved.

96. In order to bill code 77470, the provider must document the medical necessity for such code. It is expected that documentation will be maintained in the patient's medical record to support the medical necessity for this procedure.

97. Vantage physicians for years routinely have billed code 77470 for many radiation patients they treat without providing the necessary documentation in the patient record which justifies the increased billing for CPT code 77470. Vantage's philosophy has essentially been that 77470 is a "tree" code that may be added to any IMRT treatment in order to increase billings.

98. There are numerous patients in which no additional documentation is contained in the patient chart that supports the medical necessity of the use of procedure code 77470.

99. Vantage has continued to knowingly bill code 77470 on many of its IMRT

patients, without properly documenting the necessity for such code in the records and receiving payment from the United States for this billing. Without the proper documentation in the patient's record, billing for CPT code 77470 is medically unnecessary and therefore not reimburseable.

100. The knowing submission of claims forms to CMS and its intermediary WPS for payment relating to services by Vantage and Kabare identified under CPT code 77470, which are not medically necessary, constitutes a false claim for which the United States Government is entitled to damages.

E. Improper Billing of CPT 77370 - "Special Medical Radiation Physics Consultation".

101. A qualified medical physicist is a professional who specializes in the application of physics to medicine. Medical physicists may help develop improved imaging techniques, collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location.

102. It is anticipated that a medical physicist will cooperate with the radiation oncologist in preparing a treatment plan for an IMRT patient. In general, the oncologist will assign specific radiation dose requirements and dose constraints, taking into account the tumor volume and location and the surrounding organs. The medical physicist, or a dosimetrist under his supervision, will then use a treatment planning computer to calculate a complex multibeam treatment plan that will deliver the target dose and satisfy the dose constraints. The medical physicist's role under normal circumstances is taken into account in the various payment codes

related to IMRT planning and not to be used as a separate charge.

103. In certain circumstances, however, a special problem or circumstance may require the radiation oncologist to request that a qualified medical physicist provide a special consultative report or specific physics service for an individual patient. For example, a patient may have a pacemaker that must be taken into account in developing a treatment plan. In such cases, the physicist will prepare a full consultative report and provide it to the physician, who acknowledges and relies upon the report in providing care to the patient. The provider may obtain additional payment for this special consult by using CPT code 77370.

104. According to the LCD, 77370 is used when the complexity of the treatment plan is of such magnitude that a thorough analysis is necessary to address a specific problem, or when the service to be performed requires the expertise of a qualified medical physicist. The clinical indication that justifies the request for the special physics consultation must be documented, reviewed, signed and dated by a physician. Documentation of the physician's request and the physics report, as well as the physician review of the report, is necessary.

105. Rather than only using the code in special circumstances, however, Vantage has established a policy of billing for a special physics consult for many IMRT patients, regardless of medical necessity. In many cases, the medical record contains no formal request by the oncologist for a special physical consult.

106. Relator has first hand knowledge of the billing being performed in a false manner as he was the physicist for a significant number of patients for which Vantage billed CPT code 77370 for services that were not sufficiently documented and signed by the physician and therefore medically unnecessary.

107. Vantage's routinely used code 77370 to obtain additional payments for nearly all IMRT patients regardless of the need for a special physics consult is false.

108. Vantage's internal audits identified a practice of improperly and routinely billing code 77370 for its patients. All special physics consult reports are documented via a template and are worded exactly the same for all patients. By definition, special physics reports, 77370, are meant to be customized and "special" for each patient's particular case.

109. Moreover, Vantage has consistently used a new graduate physicist to perform services under CPT code 77370. However, Vantage has used its Vice President, Dr. Aissi, and his digital signature in billing CPT 77370 for this graduate physicist. Vantage has 34 centers throughout the United States, and it has used Dr. Aissi's digital signature to bill for CPT code 77370 when he was not involved in the care of a specific patient.

110. The knowing submission of claims forms to CMS and its intermediary WPS for payment relating to services identified under CPT code 77370 that were either not performed or were not medically necessary because no medical document exists to support the billing for the extraordinary expenses, constitutes a false claim for which the United States Government is entitled to damages.

F. Improper Billing of CPT 77331 - "Special Dosimetry".

111. This CPT code is used to report the measurement of radiation dose at a given point using special radiation monitoring and measuring devices such as thermoluminescent dosimeters, solid state diode probes, and special dosimetry probes, other dosimetry probes or film dosimetry. This procedure is not to be routinely performed each time the patient is treated. (Exhibit "E", Subsection 5, discussing CPT code 77331). It would be expected that the utilization of this

procedure would correspond with the level of complexity of the clinical treatment planning services provided for the patient. This service is typically billed once per port when the physician determines that it is necessary to have a measurement of the amount of radiation that a patient has actually received at a given point, with the final results being utilized to accept or modify the current treatment plan.[8] The monitoring devices utilized for measuring and monitoring can include Thermoluminescent Dosimeters (TLD), solid state diode probes, special dosimetry probes or film dosimetry. (Exhibit "E", Subsection 5, discussing CPT code 77331). The physician must specify the type of special dosimetry in order to bill CMS for the procedure. Vantage has systematically used this code inappropriately without having he physician specify the type of special dosimetry to be used.

112. Since January 2010, Vantage has been pressuring their centers to utilize this code for each filed dosimetry. This practice resulted in billing this code for each patient on the average three times rather than a single occasion. Vantage has been instructing staff to take measurements of each field and to repeat the measurement if there are more than one plan for each patient. These unnecessary measurements are without justification and/or performed by unqualified personnel.

113. Vantage also has had physicists sign off on the reports once a week when the reports should be signed off at the time the procedure is performed. The knowing submission of claim forms requesting payment under CPT 77331 for services rendered under this CPT without specifying the type of special dosimetry in the records by a physician is medically unnecessary

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[8] The term port refers to the site on the skin where the radiation beam enters the body.

and therefore is a violation of the FCA.

G. IMRT For Breast Treatment.

114. Vantage has routinely billed CMS and its fiscal intermediary for IMRT procedures relating to breast treatment when the IMRT procedure was either medically unnecessary or inadequate documentation exists in the patient record to justify utilization of this procedure for payment from CMS or its fiscal intermediary.

115. IMRT treatment for breast cancer is not routine. However, it may be indicated when the tumor is in proximity to the heart. In order for a breast IMRT to be medically necessary in lieu of conventional or 3 dimensional radiation, the radiation oncologist must consider the criteria identified in Exhibit "C" and Exhibit "E", Subsection II, Part D, attached and incorporated herein. Without the memorialization of the consideration of these factors, IMRT for breast therapy is medically unnecessary for which Vantage and Kabre may not bill CMS and WPS.

116. Vantage has knowingly presented bills to CMS and its intermediary using CPT codes 77301 and 77418 requesting payment for services that were never performed or were medically unnecessary because the documentation supporting the use of this procedure for breast treatment is nonexistent.

117. The submission of claims forms to CMS and its intermediary WPS for payment relating to services regarding breast treatment identified under CPT codes 77301 and 77418 that were either not performed, or were not medically necessary, constitutes a false claim for which the United States Government is entitled to damages.

G. Other Upcoding Billing Issues.

118. Although the above practices constitute its most outrageous and routine billing improprieties, Vantage also routinely submits claims that are false for other reasons. Vantage routinely bills for complex simulations under CPT code 77290 without sufficient documentation to justify the level of complexity, and where the simulation should appropriately be billed as a simple simulation under code 77280. Vantage routinely bills electron setups as 3-D simulations under CPT code 77295 when it should almost always be billed under CPT code 77315 which is a lower reimbursement. Documentation of simulation requires a written record of the procedure, a hard copy of the x-ray film, electronic images, and evidence of image review by a physician including his signature or initials, and date reviewed before it may be billed at the higher level. (Exhibit "E", Subsection B, discussing CPT codes 77280-77295).

119. In addition, Vantage had in its employ a person named Kathleen Peters. Ms. Peters was conditionally accredited by the State of Illinois to provide radiation therapy on behalf of Vantage for its patients.

120. Ms. Peters was only accredited to provide radiation therapy at Spring Valley. A true and accurate copy of Ms. Peters' certificate is attached hereto as Exhibit "F" and incorporated by reference, indicates that Ms. Peters had obtained a conditional accreditation which was only valid for radiation therapy procedures at Spring Valley.

121. Nevertheless, Ms. Peters was directed to provide a substantial number of radiation therapy services at the Streator location where she was not licensed to provide such services.

122. Knowing the limitations on Ms. Peters' accreditation, Vantage submitted bills for services on behalf of Ms. Peters for the radiation therapy activities she performed at Streator

when she was not accredited to provide services at that location. Relator is able to identify through medical records Peter's activities at the Streator location.

123. The knowing submission of bills by Vantage for Ms. Peters' activities at Streator was false in violation of federal and state law.

124. Vantage regularly employs radiation therapists who are unqualified to perform the duties of their position. Dr. Kabre as the radiation safety officer is required monitor and ensure the qualified individuals are employed, including ensuring that they receive the appropriate amount of training and orientation. There exists a lack of documentation demonstrating the orientation or training for the radiation therapists, medical dosimetrists or medical physicists at Spring Valley and Streator. For example, Vantage hired an individual named Bryan Jayo as the manager for Spring Valley and Streator. Mr. Jayo has little or no experience in radiation therapy or billing terminology. Nevertheless, Jayo is the son-in-law of Tommy Hobbs, the Chief Executive Officer of Illinois Valley Community Hospital in Peru, Illinois, which is the planning stages with Vantage of opening a joint radiation therapy treatment center with Vantage in Illinois.

125. Vantage has also been billing the United States for charges relating to x-rays when the x-ray machine has been inoperable.

126. At Spring Valley, Vantage uses an x-ray machine that has not been operational. The use of the x-ray machine for patient care is identified by the term conventional simulation.

127. Vantage has continued to bill the United States under CPT code 77290 at Spring Valley for conventional simulation services that were not performed. This problem was recognized by Ms. Valero in her February 10, 2009, 12 chart review.

"5. Initial sim note appears that the simulation was performed on s CT in your office. Need to clarify that a "table sim" was performed in your office which includes any markers or immobilization devices and then the patient was sent to the hospital for the CT scan. You should have sim film to back up your simulation note and charge for 77290.
Corrective Action
- Investigate if film is actually taken during the table sim and educate on scoring level of sim"

128. The reason there is no sim film available is because one was never taken due to the inoperable machine. Nevertheless, Vantage knowingly billed for these services and collected payment for services not performed. These actions constitute a violation of the FCA.

VII. VIOLATIONS OF THE FALSE CLAIMS ACT

FIRST CAUSE OF ACTION
(False Claims Action - - 31 U.S.C. § 3729(a)(1))

129. The United States repeats and realleges its allegations in the preceding paragraphs as if fully set forth herein.

130. Vantage knowingly presented or caused to be presented false or fraudulent Federal Health Care Program claims for payment or approval for radiation oncology services improperly or never rendered.

131. By virtue of the false or fraudulent claims of Vantage, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, plus civil penalties of not less than $5,000 and not more than $10,000 as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990.

SECOND CAUSE OF ACTION
(False Claims Act - - 31 U.S.C. § 3729(a)(2) and 31 U.S.C. § 3729(a)(1)(B))

132. The United States repeats and realleges its allegations in the preceding paragraphs as if fully set forth herein.

133. Vantage knowingly made, used, or cause to be made or used, false records or statements - i.e., the false certifications and representations made or caused to be made by Vantage - material to a false or fraudulent claim.

134. By virtue of the false records or false statements made by Vantage, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, plus civil penalties of not less than $5,000 and not more than $10,000 as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990.

THIRD CAUSE OF ACTION
(False Claims Act - - 31 U.S.C. § 3729(a)(1))

135. The United States repeats and realleges its allegations in the preceding paragraphs as if fully set forth herein.

136. Kabre knowingly presented or caused to be presented false or fraudulent Federal Health Care Program claims for payment or approval for radiation oncology services improperly or never rendered.

137. By virtue of the false or fraudulent claims of Kabre, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, plus civil penalties of not less than $5,000 and not more than $10,000 as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990.

FOURTH CAUSE OF ACTION
(False Claims Act - - 31 U.S.C. § 3729(a)(2) and 31 U.S.C. § 3729(a)(1)(B))

138. The United States repeats and realleges its allegations in the preceding paragraphs as if fully set forth herein.

139. Kabre knowingly made, used, or cause to be made or used, false records or statements - i.e., the false certifications and representations made or caused to be made by Vantage - material to a false or fraudulent claim.

140. By virtue of the false or fraudulent claims of Kabre, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, plus civil penalties of not less than $5,000 and not more than $10,000 as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990.

FIFTH CAUSE OF ACTION
(False Claims Act - - 31 U.S.C. § 3729(h)(1))

141. The United States and Relator repeat and reallege their allegations in the preceding paragraphs as if fully set forth herein.

142. 31 U.S.C. § 3729(h)(1) provides:

> "(1) In general. Any employee, contractor, or agent shall be entitled to all relief necessary to make that employee, contractor, or agent whole, if that employee, contractor, or agent is discharged, demoted, suspended, threatened, harassed, or in any other manner discriminated against in the terms and conditions of employment because of unlawful acts done by the employee, contractor, agent or associated others in furtherance of an action under this section or other efforts to stop 1 or more violation of this subchapter."

143. During the time that Relator was employed with Vantage, Relator reported several violations identified herein to Vantage.

144. As a result of those reports, Relator was terminated from his employment. Relator requests all relief as provided under 31 U.S.C. § 3729(h)(2).

PRAYER FOR RELIEF

WHEREFORE, Relator demands judgment on behalf of the United States and prays that judgment be entered in its favor against Defendants as follows:

1. On the First, Second, Third and Fourth Counts under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Fifth Count for damages, lost wages, pre judgment and post judgment interest and special damages sustained as a result of the Defendants' discrimination, including litigation costs and reasonable attorneys fees.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

RESPECTFULLY SUBMITTED,

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Suleiman Refaei

From: Carol Rowe
Sent: Friday, December 12, 2008 3:51 PM
To: Madjid Aissi Ph. D.; Neelima Kabre, M.D.
Cc: Suleiman Refaei
Subject: FW: [Image File] Carol,KMBT200, #871

Importance: High

Attachments: KMBT20020081212153601.tif

KMBT20020081212
153601.tif (576...

Here are the records for patient [redacted] who had an I-125 Seed Implant today 12/12/2008. Per request from our Physicist, Suleiman Refaei, he wanted you to know of a "reportable situation" regarding this implant. This patient was implanted with 14500cGy instead of the prescribed dose of 8500 cGy. This was to be followed with external beam radiation at an additional 4500 cGy, at a later date.
Please let me know if you are in need of any further records. Dr. Soni was the attending Radiation Oncologist as Dr. Kabre is on vacation until December 23rd. Please advise. I just spoke with Matt, he is calling you.

-----Original Message-----
From: admin@vantageoncology.com [mailto:admin@vantageoncology.com]
Sent: Friday, December 12, 2008 2:36 PM
To: Carol Rowe
Subject: [Image File] Carol,KMBT200, #871

FROM:
Image data has been attached to
the E-Mail.

YAHOO! MAIL Classic

FW: Brachytherapy Review

Friday, October 23, 2009 6:47 AM

From: "Suleiman Refaei" <Suleiman.Refaei@vantageoncology.com>
To: refaels@yahoo.com

From: Suleiman Refaei
Sent: Wednesday, October 21, 2009 4:39 PM
To: Neelima Kabre, M.D.
Subject: Brachytherapy Review

Hello Dr. Kabre:
This is a follow up of our earlier discussion regarding Prostate Brachytherapy seed implants. The following is Dr. Kevin Redmond/ Radiation Oncologist and Dr. Mike Lamba/ Mike Lamba/Medical Physicist contact information. As I told you I spoke to both of them. Both Are welling to look at 5- 6 patient as peer review. After you called me this after noon I thought about this, I do not know what is Vantage Policy as far as peer review. If you want peer reviews then you have to contact VP of Physics as well VP of operation and the Regional Director to make sure everybody on the same page. Is there any need involve to involve the Chief of Medical staff?

redmonkp@healthall.com, kevin.redmond@healthall.com, 513-475-8274, 513-475-7777. This will give some information about Dr. Redmond http://www.med.uc.edu/departme/radiol/oncology/redmond.cfm

Dr. Mike Lamba email address is michael.lamba@uc.edu, his phone number is 513-584-9028 and 513-475-7777

I will be happy to help what ever way I can
Thanks
Suleiman

Vantage Oncology

COMPLIANCE ALERT

Date: February 24, 2009

To: Billing Coordinators/Clinical Staff

From: Nicki Valero, Compliance Director

Subject: Billing services using the name of the rendering/supervising physician on all Medicare and Medicaid (Medi-Cal) insured patients.

Effective **March 1, 2009** please make sure the services rendered each day are charged with the correct name of the physician who was in the office rendering/supervising services each day.

1. You will continue to register the patient using the name of the physician who saw the patient in consultation as the "Primary" physician and charge for the consultation using this physician.
2. From that point on, you will select the correct physician when charging for the services based on which physician actually rendered or supervised the services. You will change the "Primary Physician" whenever you charge for services if the rendering or supervising physician is not the "Primary Physician" listed on the screen.
3. The written prescription codes 77261-77263 and the STP code 77470 should be charged under the name of the doctor who wrote the prescription or what you call the clinical treatment plan.
4. Treatments are billed out under the name of the physician who was in the office supervising the treatments that day. If two or more doctors are in the center then you should choose the primary doctor if present, if not then you may choose either doctor.
5. IGRT must be charged out using the name of the physician who was in the office supervising and signing off on the shift/image. Virtual review outside the office where the service was performed does not meet the supervision requirements of IGRT.
6. For dosimetry and physics work, you will bill the services using the name of the rendering physician who signs and approves the plan and QA work. Charge 77336 using same doctor who performed the OTV for that same week.
7. Any services the physician performs face-to-face with the patient- like OTV, follow-up visits- must be billed under the name of the physician who performed the service.
8. CT/Simulation or Simulation must be billed using the name of the rendering/supervising physician who was present in the office when the service was rendered. This same rendering/supervising physician should be the physician who signs all CT/Sim or Sim notes/documentation.
9. Port films or pre-port simulations also require the services to be billed using the name of the rendering/supervising physician who was in the office that day and signed off on the film(s).
10. You must apply this rule to all Medicare, Medicaid (Medi-Cal) and any other government insurance like TriCare for Life and Veterans Benefit programs. The rule does may not apply to commercial insurances.
11. If a new doctor sees a Medicare or Medicaid (Medi-Cal) or government insurance patient and their provider numbers have not been received yet, you will need to hold the claims until the new doctor provider number is received. They may not borrow numbers from other group practice physicians.
12. If a locum physician is present in the office, you will charge all services out under the name of the physician who the locum physician is covering for. If Medicare, you will need to use the modifier Q6 to explain that a locum physician actually rendered or supervised the services.

TELETHERAPY ISODOSE PLANS

Basic definitions

77305 Isodose Plan, Simple

77310 Isodose Plan, Intermediate

77315 Isodose Plan, Complex

Coding Guidelines

- ✓ Usually only one isodose plan may be reported per course of therapy.
- ✓ In some cases it may be necessary to have two isodose plans for treatment purposes such as a breast plan with and without wedges or a simple plan for a supraclav in an irregular form and a complex plan for the tangents due to wedges and possible custom blocking. Both plans are billable if used for treatment but must be printed and charged on separate dates.
- ✓ If the initial plan is a 3D and the boost or cone down is planned off the same CT dataset then a complex isodose plan should be charged for the boost or cone down plan.
- ✓ If the initial plan is an IMRT and the boost or cone down is planned off the same CT dataset then a complex isodose plan should be charged for the boost or cone down plan.
- ✓ All isodose plan codes are included in 3D 77295 and IMRT 77301 and cannot be charged with these codes if for the same volume of interest.

Documentation Guidelines

- ✓ An isodose plan with isodose lines signed and dated by the physicist and physician is required documentation.

Scoring

Complex Isodose Plan 77315

- 5 or more ports converging on one treatment area, custom blocking is employed or wedges with any treatment.

Intermediate Isodose Pan 77310

- 3 or more treatment ports directed to a single treatment area, simple or no blocking may be utilized.

Simple Isodose Plan 77305

- One or two parallel opposed unmodified ports directed to a single area, and irregular plans.

Basic Dosimetry Calculation

Basic definitions

77300 **Basic Dosimetry Calculation**

Coding Guidelines

- ✓ Multiple Calculations may be required throughout the course of therapy due to:
  1. Weight gain or loss;
  2. Monitoring of sensitive organs;
  3. Tumor volume change, or;
  4. Dose or other changes in the patients care.
- ✓ The calculation of different projections for the same site is considered to be included as one calculation if all treatment parameters other than beam angle are the same. Example:

  If in a 4 port box treatment of the pelvis, the anterior and posterior opposed ports and the right and left lateral opposed ports are treated. If the anterior and posterior ports are identical in size, shape and depth, they are considered to be one calculation. However, if different, two calculations may be reported. The same holds true for the lateral ports. If two entirely separate sets of calculations are performed in AP or lateral opposed fields because of irregular fields that require variable blocking, weighting or depth, two separate calculations should be reported.
- ✓ On all but IMRT plans you may charge for the calcs generated either by the treatment planning computer, hand calcs or MU calcs but not all three. Re-calculation by a different methodology does not warrant a second charge.
- ✓ On IMRT you may only charge for the MU calcs.

Documentation Guidelines

- ✓ Identification of all body area(s) being treated and requiring Dosimetry calculations
- ✓ An explanation of any additional calculations
- ✓ The calculations of the radiation dose distribution (i.e., the radiation dosage and length of time to deliver the dose) either by hand or computer or MU.

Blocks/Devices

Basic Definition

77332 Blocks/Devices, Simple

77333 Blocks/Devices, Intermediate

77334 Blocks/Devices, Complex

Coding Guidelines

- ✓ Multiple blocks/devices may be billed on same day.
- ✓ May only charge once for each device (cannot bill for same block/device everyday it is used).
- ✓ Rule is one block/device per port (if complex block and wedge used may only bill for the complex block).
- ✓ If the port is split, charge for only 1 block/device per port.
- ✓ MLC is considered a complex block.
- ✓ If devices of two separate levels are used on a port charge for the highest level block/device used on the port.
- ✓ Changes in the configuration or the treatment portal at some later date may require the redesign and/or fabrication of a new block/device such as cone down or boost. Necessity for new blocks must be documented.
- ✓ Typical course of therapy will require up to 5 blocks/devices, however, IMRT, prostate, head & neck cases may require upwards of 8 or more.
- ✓ Opposed portal pairs where one film is used (film is flipped) to cut blocks for the opposed ports then only one professional charge is allowed. You may bill a technical code for both blocks to cover time and materials.

Documentation Guidelines

- ✓ The medical record must demonstrate the physician's involvement in the design, supervision and construction.
- ✓ The physician must sign an order for each device used and note the medical necessity of the device(s).
- ✓ Documentation of all immobilization devices must be documented in the simulation note.

SCORING

Complex Block/Device 77334

- Custom blocking/immobilization devices designed specifically for one patient and not re-usable are included in this category.
- Special shields for eyes, compensators, wedges, molds, and casts, aquaplast, alphacradle, vac loc bags, MLC, irregular cerrobend, rice box, wax molds

Intermediate Block/devices 77333

- Blocks utilizing cast or pre-made standard shaped, blocks, stints, standard size blocks or special bolus are included in this category.

Simple Block/Device 77332

- Simple bolus, breastboard (wingboard is not a billable), simple shield independent jaws or asymmetric collimation.
- Usually no special fabrication is necessary for these blocks/devices or pre-made devices.

DOCTOR'S TREATMENT PLANNING PRESCRIPTION

Basic Definitions

77261 **Radiation Treatment Planning Prescription- Simple**

77262 **Radiation Treatment Planning Prescription- Interm**

77263 **Radiation Treatment Planning Prescription- Complex**

Coding Guidelines

- ✓ Treatment planning is usually a one-time charge per course of therapy.
- ✓ Multiple treatment plans for a single course of treatment are usually not allowed.
- ✓ If a new problem is discovered during the course of treatment and a new area is planned then a second treatment planning prescription charge is allowed. There is usually a new diagnosis code for the new site unless additional mets site.
- ✓ If dual modalities are planned or considered from the beginning (Prostate Seed Implant followed by IMRT beam treatments for example) then only one treatment planning prescription code is allowed.
- ✓ Routine boost or cone down is not too be billed with a new treatment planning code.
- ✓ There is no time restriction on the interval between courses of radiation therapy. Each new course of radiation therapy will require a new diagnosis and new treatment planning prescription to be performed.

Documentation Requirements

- ✓ Documentation must be maintained in the patients medical record to include evidence of planning to include:
  1. Definition of the field of treatment
  2. Selection of Beam Energy to be used
  3. Selection, or combination of treatment modalities to be used
  4. Identification of the tumor volume
  5. Identification of critical structures, if any, in proximity to the tumor volume
  6. An indication of the time/dose plan of therapy
  7. An indication of the estimated final target dosage
  8. An indication of any limiting dosages or dose points
  9. Method or technique (Conformal, Conventional 3D, IMRT, Electrons)
  10. If IMRT is to be used, a note of medical necessity must be in the file comparing IMRT to 3D

Scoring

77263 – if any of the following apply:

- Planning for IMRT, conformal or conventional with custom blocking (includes use of MLC, custom bolus)
- Use of Electrons as a sole modality (primary)
- Three or more areas or volumes to be planned
- Moving portals such as rotation or arc planned
- Conformal shaped blocks may be planned to more than 4 ports
- 5 or more ports planned for a single volume
- Custom blocked, primary treatment with electrons
- One or more complex isodose curves required to plan the course of treatment
- Use of brachytherapy either as a sole modality or in combination with external beam
- Concurrent Chemotherapy
- Retreat or overlap of previously radiation therapy port or field must be considered
- Complex fixation devices such as alpha cradle, aquaplast, eye shield, plaster mold.
- Combined modalities (electrons and photons)

If none of the above applies go to the next level down 77262.

Scoring Continued

77262 – if any of the following apply:

- Two separate areas or volumes are planned
- Custom blocking must be planned for a relatively simple treatment
- Four or fewer ports per single volume of treatment to be planned
- Although plan is simple, doctor had to consider the consequences of treating sensitive structures
- Simple immobilization device such as bite block or breast board used
- Simple Isodose Curve to be planned
- The patient may be pre-operative or post-operative
- Microdosimetry, TLD, Diode planned
- Wedge or compensator to be planned for relatively simple treatment plan
- Use of electrons planned as part of the treatment (boost)
- Hyperfractionated course of therapy planned
- Chemotherapy received within 3 months prior to starting therapy
- Abutting fields but with no overlap of portals
- Tangential portals planned without custom blocking
- 1 or 2 portal constructions are planned for a given treatment area
- Migration or portal junction lines to avoid over or under treatment of abutting fields is necessary
- Patient is on a scientific protocol study

If none of the above applies then go to the next level down 77261.

77261- if any of the following apply

- Single area or volume to be planned for treatment
- Simple or no blocking or bolus to be planned
- Simple MLC blocking- independent jaw motion or asymmetric collimation
- Use of a single, unblocked electron port for small skin lesion
- X-ray photons, any energy, cobalt 60 teletherapy, kilovoltage, any energy
- A single central axis dose point is all that is required

3D (Simulation) PLANS

Basic definitions

77295 **Three Dimensional (Simulation) Treatment Planning**

Coding Guidelines

- ✓ May be billed once per course of treatment per treatment volume.
- ✓ If cone down or boost is planned off the original CT dataset then bill for a complex isodose 77315
- ✓ If cone down or boost is planned off a new CT dataset then you may charge for a second 3D plan 77295 with a note from the physician as to why a new CT dataset was medically necessary.
- ✓ The same dataset can be used to create an initial 3D plan and then an IMRT plan for the cone down or boost.
- ✓ The same dataset can be used to create and initial IMRT plan and then a 3D plan for the cone down or boost.
- ✓ You cannot bill both 3D 77295 and any isodose plan code for the same volume of interest. All three isodose plan codes 77305, 77310, and 77315 are included in 77295.
- ✓ You may charge for a 3D plan to the breast and an isodose plan for the subclav as long as the plans are printed and charged on separate days.
- ✓ You may charge for the CT/Simulation 77014-TC and one of the following-77280, 77285, or 77290(check Simulation guidelines for scoring) as long as they are not performed on the same day the 3D plan 77295 is printed and charged.
- ✓ If patient is an emergency and both CT/Sim and 3D plan are all created on same day bill for the 3D plan and not for the CT/Sim codes.

Documentation Guidelines

- ✓ Documentation must consist of a computer generated plan with a DVH and/or dose cloud distribution and appropriate critical structures with evidence of review by the physician designated by the physician's signature or initials and date and signature or initial of the physicist.

Criteria for 3D

One or more of the following must be documented for 3D to be clinically warranted;

- ✓ The volume of interest is irregular and in close proximity to normal structures that must be protected;
- ✓ The volume of interest is in such a location that its parameters can only be defined by MRI or CT;
- ✓ The final boost volume of interest must be constructed to the exact tumor volume with its irregular configuration;
- ✓ Multiple or conformal portals are necessary to cover the volume of interest with close margins and protect immediate adjacent structures;
- ✓ Beams eye view of multiple portals must be established for conformal therapy delivery;
- ✓ An immediately adjacent area has been irradiated and abutting portals must be established with high precision;
- ✓ 3D reconstruction of the tumor volume and the critical structure volume in brachytherapy cases is used to develop DVH for the tumor and critical structures.

External Beam Treatment Level Scoring Tool

Oct-08

1. First select the code group from Section 1 based on criteria listed

2. The go to Section 2 to select the code based on energy used (should match color of section 1)

Section 1		
CPT Code	Description	Criteria for Level
77401	Radiation treatment delivery, superficial and/or no ortho voltage	Single Port, parallel ports, no devices or simple devices
77402 77403 77404 77405 77406	Radiation treatment delivery, single treatment area	Single Port, parallel ports, no devices or simple devices
77407 77408 77409 77411	Radiation treatment delivery, two separate areas	Two separate areas treated, three or more ports on a single area, multiple non-complex devices, use of custom bolus
77412 77413 77414 77416	Radiation treatment deliveery, three or more separate treatment areas	Three or more separate areas treated, custom devices, rotational beam, compensators, electron beam, (e.g., electrons, neutrons), tangential ports, use of complex devices

Section 2					
Tier	Kilovoltage	< 5 MV	6-10 MV	11-19 MV	> 20 MV
Simple	77401	77402	77403	77404	77406
Intermedia	77401	77407	77408	77409	77411
Complex	77401	77412	77413	77414	77416

Example: a 10 MV level treatment with complex blocking would be 77413

Example: a 18 MV with custom bolus only would be 77409

Example: a 6MV open with no blocks would be 77403

IGRT Guidelines

Basic definitions

76950 Ultrasound Based Guidance for Placement of Radiation Fields

77014 CT Based Guidance for Placement of Radiation Fields

77421 X-ray Based Guidance for Placement of Radiation Fields

0197T Electromagnetic based IGRT (Calypso) (new technology code)

Coding Guidelines

- ✓ May be billed once per day
- ✓ CPT codes 77014 and 76950 may only be billed globally if physician signs the daily shift/image. If the doctor does not sign the shift/image daily bill only the technical component.
- ✓ CPT code 77421 requires the physician to sign the document daily to bill the code. If the doctor does not sign the daily shift/image do not charge the technical or the professional component.
- ✓ CPT II code 0197T requires same documentation as 77421 as records may be requested to determine the amount to be reimbursed. New technology codes have no established fee schedule.
- ✓ Centers with electronic portal imaging technology may report port film verification using 77417.
- ✓ The use of orthogonal portal imaging to locate markers in and of itself would not fulfill the required criteria.
- ✓ The stereoscopic images have to be fuse and registered with the pre-treatment digitally reconstructed radiographs (DRR's) and the required shifts calculated and adjustments made to correct if any.

Documentation Guidelines

- ✓ Documentation to support the technical component of 76950-TC is a copy of the shift/image each time the code is charged.
- ✓ Documentation to support the professional component of 76950-26 (or global) requires a physician signature on the shift/image each time the professional component is charged.
- ✓ Documentation to support the technical component of 77014-TC is a copy of the shift/image each time the code is charged.
- ✓ Documentation to support the professional component of 77014-26 (or global) requires a physician signature on the shift/image each time the professional component is charged.
- ✓ Documentation to support 77421 & 0197T (global only may be charged) is a physician signature on the shift/image each time the code is charged.
- ✓ Do not bill 77421-TC alone as the code may only be charged globally due to the supervision level required to bill the technical component.

IGRT Considerations

IGRT may be considered when using the following:

- ✓ 3D Conformal Therapy (Please see Medicare criteria for 3D)
- ✓ IMRT Therapy (Please see Medicare criteria for IMRT)
- ✓ Stereotactic Radiosurgery
- ✓ Stereotactic Body Radiation Therapy
- ✓ Target volume is in close proximity to critical structures that must be protected
- ✓ The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures
- ✓ An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision
- ✓ Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment

IMRT PLAN

Basic definitions

77301 Three Dimensional (Simulation) Treatment Planning

Coding Guidelines

- ✓ May be billed once per course of treatment per treatment volume.
- ✓ If cone down or boost is planned off the original CT dataset then bill for a complex isodose 77315
- ✓ If cone down or boost is planned off a new CT dataset then you may charge for a second IMRT plan 77301 with a note from the physician as to why a new CT dataset was medically necessary.
- ✓ The same dataset can be used to create an initial 3D plan and then an IMRT plan for the cone down or boost.
- ✓ The same dataset can be used to create and initial IMRT plan and then a 3D plan for the cone down or boost.
- ✓ You cannot bill both IMRT 77301 and any isodose or 3D 77295 plan code for the same volume of interest. All three isodose plan codes 77305, 77310, 77315 and 3D 77295 are included in 77301.
- ✓ You may charge for a IMRT plan to the breast and an isodose plan for the subclav as long as the plans are printed and charged on separate days.
- ✓ You may charge for the CT/Simulation 77014-TC and one of the following-77280, 77285, or 77290(check Simulation guidelines for scoring) as long as they are not performed on the same day the IMRT plan 77301 code is printed and charged.
- ✓ If patient is an emergency and both CT/Sim and IMRT plan are all created on same day bill for the IMRT plan and not for the CT/Sim codes.

Documentation Guidelines

- ✓ Documentation must consist of ***all*** of the following:
  1. Patient meets at least one of the criteria listed below under "Criteria for IMRT"
  2. A statement by the treating physician documenting the special need for IMRT on the individual patient in question, rather than performing conventional or 3D treatment planning and delivery.
  3. The physician's prescription must define the goals and the requirements of the treatment plan including the specific dose constraints for the target(s) and nearby critical structures.
  4. A signed and dated IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV)and surrounding normal tissue using either dynamic MLC or segmented MLC with an average number of "steps" required to meet IMRT delivery is 5 or inverse planned IMRT solid compensators to achieve IMRT delivery
  5. The target verification methodology that includes all of the following:
     a. Documentation of the CTV and the PTV.
     b. Documentation of the immobilization and patient positioning.
     c. Means of dose verification and a secondary means of verification.
  6. The MU's generated by the IMRT plan must be independently checked before the patient's 1st treatment
  7. Documentation of fluence distributions re-computed in a phantom is required.
  8. Documentation that accounts for structures moving in and out of the high and low dose regions created by respiration. Voluntary breath holding ***is not*** considered appropriate and the solution for movement can best be accomplished with gating technology.

Criteria for IMRT

At least ***one*** of the following must be documented for IMRT to be clinically warranted;

- ✓ Important dose limiting structures adjacent to, but outside the PTV, are sufficiently close and require IMRT to assure safety and morbidity reduction;
- ✓ An immediately adjacent volume has been irradiated and abutting portals must be established with high precision;
- ✓ The GTV margins are concave or convex and in close proximity to critical structures that must be protected to avoid unacceptable morbidity;
- ✓ Only IMRT techniques would decrease the probability of grade 2 or 3 radiation toxicity as compared to conventional radiation in greater than 15% of radiated similar cases.
- ✓ IMRT is covered when the tumor tissues lies in areas associated with target motion caused by cardiac and pulmonary cycles and IMRT is necessary in order to protect adjacent normal tissues.
- ✓ IMRT is the only option to cover the volume of interest with narrow margins and protected immediately adjacent structures.
- ✓ Only IMRT can produce dose distributions that can cover extremely concave target geometries.

Sulemow

Vantage Oncology

February 10, 2009

Compliance Review Summary- Spring Valley

A review of 12 charts was conducted on Spring Valley, IL center. The following risk areas were identified:

1. If charging STP for concurrent chemo you must mention how the concurrent chemo is or is not affecting your patient in your OTV notes or at least in the end of treatment summary.
   Corrective Action
   - Educate on documentation requirements for OTV

2. Wingboards are not a billable device. Being charged as simple device 77332.

3. Planning note contains information about the initial planning sim and if used, the immobilization device. This same note also contains a statement about the block check simulation but is dated the same date as the initial planning sim which is before the plan was even created and is also dated on a different date than the block verification simulation is actually performed and charged. The pre-port simulation requires a note signed by the doctor which is dated the date performed and charged.
   Corrective Action
   - Educate on simulation documentation requirements and offer forms
   - Stress the importance of charging for services on date that matches supporting documentation

4. Boost complex sim 77290 charged without documentation in the file. If this was a sim performed on the patient or a clinical sim you still need a sim note signed by the physician. If this boost sim code is for block verification then the code is 77280 which also requires a sim note.
   Corrective Action
   - All block verifications, whether for initial plan or boost plan, are simple 77280
   - If 77290 is being charged for a clinical sim, then a sim note signed by the doctor is needed

5. Initial sim note appears that the simulation was performed on s CT in your office. Need to clarify that a "table sim" was performed in your office which includes any markers or immobilization devices and then the patient was sent to the hospital for the CT scan. You should have sim film to back up your simulation note and charge for 77290.
   Corrective Action
   - Investigate if film is actually taken during the table sim and educate on scoring level of sim

6. OTV notes are poor and do not address the required 7 elements. Handwriting is not legible and Medicare may disallow. Some notes only reflect the nurse's assessment with doctor only signing the note. OTV requires face to face with the patient and a physical exam to be documented each week.
   Corrective Action
   - Educate on Medicare requirements for OTV 77427

7. You should charge the blocks and calcs on same day as the plan as the supporting documentation for the calcs and blocks are in the treatment plan or QA work for the IMRT plan.

8. Did billing department instruct you to use modifier -76? This modifier is not really used in this fashion unless your Medicare carrier is instructing you to bill in this fashion.

9. IMRT note of medical necessity needs to specify the critical structures or reason why IMRT was best method for that particular patient compared to 3D per Medicare LCD.
   Corrective Action
   - Review Medicare IMRT policy documentation requirements

10. Missing documentation of delivery to a phantom for QA of the IMRT plan.
    Corrective Action
    - Review Medicare IMRT policy documentation requirements

11. X-ray based IGRT 77421 must be billed globally or not at all. Doctor must sign off on the shift/image daily for the code to be charged. The Shift Sheet demonstrates the physician only signed off weekly. The technical component of 77421 has a supervision level "3" meaning in direct attendance and the documentation must support this level of supervision.
    Corrective Action
    - Review supervision and documentation requirements for 77421 - related sign off on Shift Sheets

12. IMRT plans must have an independent MU calc for each beam before the plan is used to treat the patient. If you create an IMRT boost plan you must have documented MU calcs for each of the boost ports to charge the calcs 77300. Patient [redacted] has the phantom QA for the initial and boost but only independent MU calcs for the initial IMRT plan.
    Corrective Action
    - Review Medicare IMRT policy documentation requirements

13. Physics consultation performed for QA or verification of the IMRT plan is not allowed as this work is included in the IMRT plan code 77301. Physics consultation may be performed with IMRT if request from physician is clearly documented and for a reason other than QA or verification of the IMRT plan.
    Corrective Action
    - Review ASTRO clarification of what is included in IMRT plan code 77301

14. Doctor's written prescription or what you call the Doctor's Clinical Treatment Planning must be charged on a date that matches the supporting documentation. The Doctor's prescription is located on the front of the tri-fold treatment record under "Radiation Therapy Prescription".

15. Cannot charge for both a Brachytherapy plan 77328 and a 3D plan 77295 on the same day for prostate seed implant. Charge for the plan that was used which appears to be the 3D plan.
    Corrective Action
    - Review CCI edits
    - Assist with a custom charge template for prostate seed implants

16. No procedure note in file to support prostate seed implant charges 77778 and 77790.

17. If boost plans are planned at a later date than the initial plan and planned off the same CT dataset a complex Isodose 77315 may be charged for the boost plan. If boost plan is planned off new CT (with note as to the medical necessity of repeat CT) then you may charge a second 3D 77295 or second IMRT 77301.

Have to do QA before use

77370 - IMRT (No Physics Consult)

Not billable

Nicki Valero, CHC
Compliance Director
Vantage Oncology

LCD for Radiation Oncology Including Intensity Modulated Radiation Therapy (IMRT) (L30316)

Contractor Information

Contractor Name

Wisconsin Physicians Service Insurance Corporation

Contractor Number

00951, 00952, 00953, 00954, 52280, 05101, 05201, 05301, 05401, 05102, 05202, 05302, 05402

Contractor Type

Carrier - FI - MAC

LCD Information

LCD ID Number

L30316

LCD Title

Radiation Oncology Including Intensity Modulated Radiation Therapy (IMRT)

Contractor's Determination Number

RAD-014

AMA CPT / ADA CDT Copyright Statement

CMS National Coverage Policy

Medicare Claims Processing Manual
Chapter 13 - Radiology Services and Other Diagnostic Procedures

70 - Radiation Oncology (Therapeutic Radiology)
70.1 - Weekly Radiation Therapy Management (CPT 77419 - 77430)
70.2 - Services Bundled Into Treatment Management Codes
70.3 - Radiation Treatment Delivery (CPT 77401 - 77417)
70.4 - Clinical Brachytherapy (CPT Codes 77750 - 77799)
70.5 - Radiation Physics Services (CPT Codes 77300 - 77399)

Formerly:
MCM 15021 Transmittal 1787, 01/24/2003
MCM 15022 Payment Conditions for Radiology Services.
MCM 5262 Payments Under the Fee Schedule for Radiologist Services.

Primary Geographic Jurisdiction

Oversight Region

Original Determination Effective Date

For services performed on or after 08/16/2009

Original Determination Ending Date

Revision Effective Date

For services performed on or after 10/18/2010

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

LCD Description
Radiation oncology is the specialty of medicine that utilizes high-energy ionizing radiation in the treatment of malignant neoplasms and certain non-malignant conditions. It uses several distinct therapeutic modalities: teletherapy, brachytherapy, hyperthermia, and stereotactic radiation. These may be directed at either malignant or benign lesions.

Definitions: Because some words are used interchangeably and some payments are allowed based on these word uses, this policy will stipulate the following definitions:

Port, Portal: These words are synonymous and refer to the site on the skin where the radiation beam enters the body. Field, often used as a synonym for port, will not be used in this policy.

Volume of interest: This phrase refers to that volume within the body to which the radiation therapy is directed. In this policy, volume of interest is never synonymous with port and is preferred to other terms with the same presumed meaning because it is the phrase most commonly used by radiation oncologists. While this policy recognizes the legitimate use of these terms in other documents, this policy will use the term volume of interest in place of the terms treatment volume, area of interest, target site, and field. However, all CPT Code descriptions that use these terms are copyrighted by the AMA, and will not be changed. For further definitions see Section: Comments

Indications and Limitations of Coverage and/or Medical Necessity
Radiation oncology services are considered medically reasonable and necessary when the following conditions are indicated and documented in the patient's medical records.

I. Conventional External Beam Teletherapy including 3-D Conformal Teletherapy

A. Tumor Mapping and Clinical Treatment Planning (CPT codes 77261 - 77263)

Clinical treatment planning and tumor mapping are crucial to identifying the location, extent, and volume of tumor(s) to be treated and all critical structures surrounding them. The physician plans the appropriate course of radiation therapy, which will allow for maximum benefit while protecting surrounding tissues and structures. Clinical treatment planning may involve ordering and interpreting special tests such as lymphangiography, CT scan, nuclear medicine study, ultrasound, MR scan, and/or surgical exploration with biopsy and markers placed, for the purpose of treatment planning, and tumor localization, virtual reality-based 3D simulation system or other dedicated diagnostic x-ray, ultrasound, or nuclear medicine equipment that has been modified to localize treatment volumes in order to define the area that requires treatment.

Clinical treatment planning requires consideration of: treatment time/dose determination, choice of modalities, determination of number and size of treatment portals, planning of appropriate devices, sequencing and combination of modalities, and correlation of physical exam findings with imaging studies and special tests to delineate precise clinical location of the tumor or area at risk.

Clinical Treatment planning is a one-time charge per course of therapy. Billing for multiple treatment plans for a single course of treatment is not allowed. This is a professional service only and the physician is responsible for all of the technical aspects of the treatment planning process.
Report CPT code 77261 when the volume to be treated is clearly defined and easily encompasses the tumor while excluding normal tissue and structures. If a patient requires therapy to a new volume of interest a separate treatment plan may be allowed and appropriate documentation should be available upon request.

Simple planning requires no interpretation of special tests and involves no more than one critical structure or volume of interest.

77261 Therapeutic radiology treatment planning; SIMPLE
Criteria Level of Care
Special tests None
Modality External photon beam as sole modality
Treatment time/dose considerations Standard fractionated (once per day) treatment. Normal tissues may be included, and normal tissue tolerance may be exceeded, if patient survival is presumed to be limited.
Ports Single area of interest in a single port or simple parallel opposed ports
Devices None, or single set of any type of pre-made devices. A "set" may include multiple loose blocks placed on a tray or fixed to the tray by connecting devices. Immobilization devices not designed or manufactured for a specific patient.

Report CPT code 77262 when there is an intermediate level of planning difficulty. Two separate volumes of interest (non-contiguous) are involved.

Critical or sensitive organs that need protection require special tests for localization of tumor volume. Not more than two critical structures are involved when planning the optimum course of treatment

77262 Therapeutic radiology treatment planning; INTERMEDIATE
In order to bill this treatment planning code, at least two criteria must be met.
Criteria Level of Care
Special tests interpreted necessary to define tumor volume for treatment purposes Fluoroscopy (other than for simulation purposes), ultrasound, which are necessary to define tumor volume for treatment purposes
Modality External photon beam as sole modality
Treatment time/dose considerations Standard fractionated (once per day) or special time-dose considerations (e.g. hyperfractionated) treatment. The number of critical/sensitive organs, will not determine complexity, per se, unless tolerance levels of these organs is reached or exceeded, and unless survival into a period of risk is reasonably anticipated. Treatment should be calculated to dose within a volume.
Ports Three or more converging ports, two separate treatment volumes
Devices Multiple sets of pre-made or manufactured generic treatment devices

Report CPT code 77263 when complex treatment planning is involved. Three or more volumes of interest may require treatment. Planning includes interpreting complex tests such as MR and/or CT localization of tumor(s). The cancer is generally complex in its distribution regardless of whether the patient is in early or advanced stages of cancer. Multiple critical areas generally require planning of special protection. Combined therapy may be required for optimum benefit such as brachytherapy, surgery, and chemotherapy. Use of electrons, tangents, wedges, customized blocks, and immobilized devices qualify for complex planning.

77263 Therapeutic radiology treatment planning; COMPLEX
In order to bill this treatment planning code, at least two criteria must be met.
Criteria Level of Care
Special tests interpreted for determination of tumor volume for treatment purposes CT, MRI, angiography, PET scan, molecular imaging
Modality External beam as primary modality (with or without electron boost*) or in conjunction with another modality (e.g. brachytherapy, hyperthermia, concurrent chemotherapy). Special or concurrent mixed beam considerations.
Treatment time/dose considerations Standard or non-standard fractionation. The number of critical/sensitive organs, will not, per se, determine complexity, but dose levels should not reach or exceed normal tissue tolerance with survival reasonably anticipated into a period of risk. Calculated doses must be to a volume.
Ports Three or more separate treatment volumes and/or rotational arcs. Tangential* and/or oblique.
Devices Blocks/immobilization devices must be customized, and, when used, must be required for appropriate clinical management. Custom blocks fabricated for palliative ports only with supporting written justification and clinical appropriateness.
*Electrons, wedges and tangents qualify for complex

B. Therapeutic Radiology Simulation - Aided Field Setting (CPT codes 77280-77295)

Radiation oncology simulation is defined as the process of determining and establishing the radiation therapy treatment portals to a specific treatment volume. Ordering and interpreting special tests may be required to assist in the field settings.

Simulation procedures 77280-77290 may be performed if medically necessary to prepare the patient for treatment planning and to ensure accurate treatment.
Following treatment planning, simulation is used to actually direct the treatment beams to the specific volumes of interest. Simulation may be carried out on a dedicated conventional simulator or CT scanner, radiation therapy treatment unit (e.g., linear accelerator), or using diagnostic imaging equipment (e.g., fluoroscopy, Pet scan, CT, MR, ultrasound or virtual reality-based 3D simulation system).

The complexity of simulation is based on the number of ports, volumes of interest, and the inclusion and type of treatment devices. However the number of films taken per treatment, the modality from which images for simulation are obtained, and the use of fluoroscopy are not
determinants of complexity. Portal changes based on unsatisfactory initial simulation(s) are not reported as additional simulations. Additional simulations may be necessary during treatment in order to account for changes in port size, boost dose, or tumor volume.

However, minor changes in port size without changes in beam or without clinical justification do not warrant an additional charge or a higher level of complexity. The inclusion of treatment devices in the simulation process typically increases the complexity. Simulation without the inclusion of devices or with any pre-made devices (e.g., blocks, immobilization) is considered simple. Custom devices elevate complexity when clinically appropriate. Documentation of simulation requires a written record of the procedure and hard copy of a x-ray film or electronic images and evidence of image review by physicians including signature or initials and data review.

The typical course of radiation therapy will require from one to three simulations. However, no more than one simulation may be reported on any given day. Frequency in excess of three simulations should be supported by documentation in the medical record and be made available upon request.

1. CPT code 77280 Set radiation therapy field
Single volume of interest with either a simple port or parallel opposed ports
Simple or no blocking
Block verification simulation
Re-simulation at a later date to verify the accuracy of custom blocks, prior to beginning a treatment is considered a simple simulation (CPT code 77280).

2. CPT code 77285 Set radiation therapy field
Simulation of three or more converging ports, or two separate volumes of interest.
Multiple blocks are covered when clinically necessary.

3. CPT code 77290 Set radiation therapy field
Three or more volumes of interest, or when one or more of the following conditions exists:
- Rotation or arc therapy
- Complex blocking or custom made shielding blocks or compensators, or custom immobilization devices, when clinically necessary.
- Any use of contrast media (e.g. body cavity, GI tract, or intravascular), when clinically necessary to define anatomic structures and volumes of interest.
- Tangential ports with/or without multiple devices.

4. CPT code 77295 Set radiation therapy field
This procedure involves three dimensional computer-generated reconstruction of tumor volume and surrounding critical normal tissue structures from direct CT scan and/or MRI
data in preparation for non-coplanar or coplanar therapy. The simulation uses documented 3-D beam's eye view volume-dose displays of multiple or moving beams. Code 77295 includes those simulation procedures done on the same day in preparation for use of coplanar therapy beams and an additional simulation charge (CPT codes 77280, 77285, and 77290) is not separately payable on the same date. CPT code 77295 also includes the work done for a teletherapy isodose plan (CPT codes 77305-77315) and accordingly CPT codes 77305-77315 must not be separately billed.
Code 77295 may be billed once per treatment course per treatment volume. Documentation in the medical record of 3-D volume reconstruction of target and critical structures and dose distribution is required.

Three dimensional simulation and treatment is clinically warranted when one or more of the following conditions exists:

a. The volume of interest is irregular and in close apposition to normal structures that must be protected.
b. The volume of interest is in such a location that it's parameters can only be defined by MRI or CT
c. The final boost volume of interest must be constructed to the exact tumor volume with its irregular configuration.
d. Multiple conformed portals are necessary to cover the volumes of interest with close margins and protect immediately adjacent normal structures.
e. "Beams eye view" of multiple portals must be established for conformal treatment delivery
f. Volume of interest bordering a previously irradiated area
g. 3D reconstruction of tumor volume and critical structure volume in brachytherapy cases to develop a DVH

Additional simulations may be required when they are done to verify plan parameters before starting new portals or boosts. In those uncommon circumstances where there is a substantial change in either patient anatomy or tumor conformation where a second CT dataset is required to produce an accurate, efficacious and safe "cone-down" plan, a second 77295 charge may be appropriate. When the physician deems this to be the case, the medical necessity for the second 77295 simulation must be documented.

C. Simulation for Brachytherapy

Radiation oncology brachytherapy simulation is defined as the process of determining and establishing the brachytherapy treatment to a specific treatment volume. Simulation is accomplished through the use of equipment such as dedicated simulator, X-ray machine, diagnostic X-ray fluoroscopy unit, or other equipment used to establish areas to be treated without delivering radiation treatment. Ordering and interpreting special tests may be required to assist in the planning and calculations of brachytherapy.

1. CPT code 77280, simple
Brachytherapy verification simulation.
Re-simulation at a later date to verify the accuracy of brachytherapy device, prior to the beginning of a treatment is considered a simple simulation (CPT code 77280). This code may be billed more than once a day since it is performed for each fraction of the treatment.

2. CPT code 77285, intermediate
This procedure involves the use of equipment such as dedicated simulator, X-ray machine, diagnostic X-ray fluoroscopy unit, custom immobilizers, or other equipment
used to establish areas to be treated without delivering radiation treatment. In general, X-ray films are obtained to verify placement and location of the brachytherapy device or sources. There is no intent to use these films for dosimetry calculations.

This code can be billed at most once a day.

3. CPT code 77290, complex
This procedure involves the use of equipment such as dedicated simulator, X-ray machine, diagnostic X-ray fluoroscopy unit, custom immobilizers, or other equipment used to establish areas to be treated without delivering radiation treatment. In general, X-ray films of different angles are obtained to determine the 3 dimensional location of the treatment point(s) or volume(s) of interest. This code can be billed at most once a day.

4. CPT code 77295, three dimensional
This procedure involves three-dimensional computer-generated reconstruction of tumor volume and surrounding critical normal tissue structures from direct CT scan and/or MRI data in preparation for brachytherapy. Three-dimensional reconstruction of the tumor volume and the critical structure volume in brachytherapy cases is used to develop DVH for the tumor and critical structures.

Documentation in the medical record should include brachytherapy treatment and 3 dimensional isodose calculations. Also see section B4.

D. Dosimetry

1. Basic Radiation Dosimetry Calculation (CPT 77300)

This service is considered to be medically necessary for each treatment port and if a patient has off-axis calculations, calculations for different depth doses, different volumes of interest, secondary film dosimetry, abutting volumes of interest, or any other situation requiring individual point calculations of radiation dosage.

Changes in a patient's weight or girth during the course of radiation treatment may necessitate dosimetry recalculation. This procedure need not be routinely performed each time the patient is treated.

Basic dosimetry calculations may be reported as many times as the calculations are performed. The typical course of radiation therapy will require from one to six dosimetry calculations, depending on the complexity of the patient's problem. However, radiation treatments to the head/neck, prostate and Hodgkin's disease may require eight or more calculations.

Medicare would expect to see ongoing documentation that would include any changes in dosimetry calculations and change in radiation treatment and frequency. Documentation requires that the calculation(s) be reviewed, signed and dated by a physician.

2. Teletherapy Isodose Plan (CPT codes 77305 - 77315)
This service is considered medically necessary for a given course of radiation therapy to a specific volume of interest. The typical course of radiation therapy will require from one to three isodose plans. Usually only one plan per volume of interest will be sufficient, even though some patients may require multiple teletherapy plans during the course of therapy. Situations that may require an extra teletherapy plan include the need to change the machine or the volume of interest. Toward the end of treatment, due to clinical variations of the patient, another plan may be required.

CPT code 77305 Simple is used when there are one or two ports parallel opposed unmodified ports directed at one volume of interest.

CPT code 77310 Intermediate is used when there are three or more ports converging on a single volume of interest. Blocking may be utilized to eliminate the beam from certain portions of the isodose plan and must be verified.

CPT code 77315 Complex planning is used when five or more treatment ports converge on a single volume of interest. Complex is used for complex planning and includes mantle or inverted Y fields, compensators, wedges, complex blocking, rotational beam or special beam considerations.

Three-dimensional stereotactic isodose planning can be classified as a complex level isodose plan and may be billed with CPT code 77315 or as part of CPT code 77295 but not with both.

The physician's documentation must be specific to the number of volumes of interest. The specific location of tumor(s) to be treated must be documented as well as the specific number of ports involved with each volume of interest treated. All isodose plans must be checked and signed by the medical radiological physicist and approved and signed by the radiation oncologist.

Up to six isodose plans may be used in a course of radiotherapy.

3. Special Teletherapy Port Plan (CPT code 77321)
This service is considered medically necessary only when a plan for a special beam consideration is required for the treatment of a neoplasm, such as the use of electrons for total skin irradiation, photons for hemibody irradiation or heavy particles. Only one plan should be billed per volume of interest. A teletherapy isodose plan (CPT code 77305-77315) may be involved with a special teletherapy port plan.

The radiation oncologist must document his/her involvement in the planning and selection of the special beam parameters and must make the final selection and initiation of the treatment process.

4. Brachytherapy Isodose Calculation (CPT codes 77326 - 77328)
Brachytherapy is used to improve control of local disease, treat areas at high risk for recurrence of malignancy, preserve vital organ function and minimize normal surrounding tissue damage.

Appliances, such as gynecological applicators, afterloading tubes, template needles, etc. are first surgically inserted by the radiation oncologists in, on, or around the tumor. Brachytherapy implants may be temporary or permanent, depending upon the type of tumor and the isotope used. Following insertion of the applicators, images are obtained for isodose calculation of the actual implant sources or using non-radioactive material in the applicator. Isodose calculations are then made which determines the amount of radiation that will be absorbed by the tumor per minute or hour. From this calculation, the treatment course can be modified if necessary by increasing or decreasing the patient's exposure time to the radioisotope. The definition of the levels of complexity of conventional clinical brachytherapy relates directly to the number of sources or ribbons utilized in the procedure. It is a generally accepted standard of practice for this code to be billed once per application (i.e. each instance a separate brachytherapy procedure is performed). For multiplane calculations on the same day CPT codes 77327 or 77328 should be used.

A plan may be required for each modification of the source strength and/or position during temporary afterloading brachytherapy and both before and after permanent seed implantation and for some temporary implants where volume pre-planning is required to determine quality and strength of sources required for the procedure.

a. CPT Code 77326 Simple: used for single plane one to four sources or ribbons application or remote afterloading brachytherapy with 1 to 8 sources or positions.
b. CPT Code 77327 Intermediate: used for multiplane dose calculations, application involving 5 to 10 sources or ribbons used, remote afterloading brachytherapy with 9 to 12 sources or positions.
c. CPT Code 77328 Complex: used for multiplane isodose plan, volume implant calculations, over 10 sources or ribbons used, special reconstruction, remote afterloading brachytherapy with over 12 sources or positions.

Many patients may be treated with a combination of both teletherapy and brachytherapy. Therefore, if a patient undergoes brachytherapy, the appropriate isodose plan codes to report are CPT Codes 77326-77328. If external beam or teletherapy is added, a separate calculation(s) is performed for the external beam dosimetry and an additional code should be reported using CPT codes 77300-77315.

5. Special Dosimetry (CPT code 77331)
This service is considered medically necessary once per port when the physician determines that it is necessary to have a measurement of the amount of radiation that a patient has actually received at a given point with the final results being utilized to accept or modify the current treatment plan.

This procedure is not to be routinely performed each time the patient is treated. It would be expected that the utilization of this procedure would correspond with the level of complexity of the clinical treatment planning services provided for the patient. The monitoring devices utilized for measuring and monitoring can include thermoluminescent dosimeters (TLD), solid state diode probes, special dosimetry probes, or film dosimetry.

The physician must specify the type of special dosimetry. When special dosimetry is employed, the usual frequency will vary from one to six, consistent with the number of dose calculations. Frequency in excess of the upper end of this range will require appropriate documentation in the medical record. This code (CPT 77331) may be used more than once per day per treatment course.

6. Treatment Devices, Designs, and Construction (CPT codes 77332-77334)
Multiple treatment devices may be billed during a course of therapy if documentation in the medical record substantiates multiple volumes of interest/portals, the use of custom-made devices, and/or the necessity of replacement devices.

Simple treatment devices (CPT code 77332) include any of the following:
-simple port blocks which include one or two hand positioned pre-made blocks
-simple prefabricated bolus that is capable of being shaped for an individual patient
-independent jaw motion or asymmetric collimation.

Intermediate treatment devices (CPT code 77333) include any of the following:

-multiple port blocks which include three or more pre-made blocks such as corner pelvis blocks, beam splitter blocks, or midline spinal cord blocks,
-stents-bite blocks, or-fabricated single patient use special bolus

Complex treatment devices (CPT code 77334) include any of the following:
-customized blocks (low temperature alloy),
-customized compensators,
-wedges, molds or casts,
-multi-leaf collimator,
-intensity modulated therapy,
-custom immobilization device (thermal plastic devices, solidifying polymers or vacuum devices),
-eye shields

Providers should bill for devices at the beginning of the treatment course and then may bill again later in the course of treatment when additional or new devices are required. Payment for one set of treatment devices may be allowed per separate port when radiation therapy is started. However, a pair of mirror imaged opposing ports, ports that direct parallel beams such as anterior-posterior or left lateral-right lateral pairs are considered, for billing purposes, to be one port. This is true regardless of the level of complexity of the devices used to create the ports. However, if these devices are significantly different from each other, then the carrier may allow payment for each of the pair of devices. It is the responsibility of the provider to determine the CPT code that most accurately describes the devices employed. At all levels of complexity, the physician must be directly involved in the design, selection, and placement of any of the devices.

It should be noted that when more than one volume of interest is being treated, it may be appropriate to bill for devices for each volume of interest. The level of complexity of these devices will be independent of each other. Custom-made immobilization devices must be billed at a complex level (CPT code 77334). These would include restraining and immobilization devices such as aquaplast and alpha cradle and vac-locs. The use of passive restraints such as straps, pillows, sandbags, etc. are not billable.

When the patient has a combination of a wedge, a compensator, a bolus, or a port block covering the same treatment portal, this would be billed as a single complex treatment device charge rather than a separate charge rendered for each of the individual items. If devices of two separate levels of complexity are utilized for the same treatment portal only the one of highest complexity will be billable.

The typical course of radiation therapy will justify from one to five charges for devices.

Treatment for prostate, head & neck and other complex therapy may require eight or more treatment devices. Frequency in excess of the upper limit must be supported by documentation in the medical record. These codes (CPT 77332-77334) may be used more than once per day per treatment course.

Code(s) 77332-77334 may be quantity billed on the same line of the 1500 claim form if a global service is billed.
When billing these codes with a 26 or a TC modifier each service has to be broken out and billed per line.

E. Medical Radiation Physics Consultation (CPT codes 77336, 77370)

CPT code 77336 - Continuing medical physics consultation: This service ensures that the treatment administered conforms to the specifications of the prescribing physician. This service includes a documented review of the patient's treatment chart and record to verify that the patient received the prescribed radiation dosage, appropriate positioning and beam orientation and radiation safety. This procedure is reported once for every five consecutive treatments delivered.

This is a weekly code and is reported once for each week of external beam radiation treatments in which at least 3 fractions have been given, or once for each 5 treatments when treatment is given more than once per day. For radiation therapy treatment that is not administered in 5 weekly fractions (such as brachytherapy or stereotactic radiosurgery) or for a course of radiation therapy consisting of one or two fractions, code 77336 may be reported.

CPT code 77370 must be used for consultative purposes when a problem or special situation arises during radiation therapy. This code requires a detailed written report describing the problem to be given to the requesting physician.

CPT codes 77336, 77370 are technical services only, and are payable by Medicare Part B only in settings in which the technical component is payable, i.e., in the freestanding radiation oncology center that employs its own radiation physicist.

Examples of problems that might justify use of this code include:
- the complex interrelationships of electron and photon ports and complex dosimetric considerations in brachytherapy, including high dose rate remote afterloader applications, intravascular brachytherapy treatments, and interstitial radioactive seed implantation;
- analysis of customized beam modification devices and special blocking procedures (and their dosimetric evaluation) to protect critical organs during treatment; or analysis of the effects of previous radiation therapy with assessment of cumulative radiation dose to critical organs.

Computation of dose to the fetus of a pregnant patient undergoing radiation therapy may be reported using this code. Special brachytherapy equipment developed by the qualified medical physicist to treat a particular patient can also be reported with this code. The qualified medical physicist will spend a considerable amount of time and effort on behalf of a specific patient and will render a customized written report (which will form part of the patient's chart) to the radiation oncologist in reference to the problem or service being addressed. Documentation of the physician's request and the physics report, as well as the physician review of that report, in the medical record is necessary. Special physics consultations should not be charged when a qualified medical physicist verifies the calculations performed by others or performs the duties of other members of the treatment team (e.g. dosimetrists).

F. Radiation Treatment Delivery (CPT codes 77401 - 77416)

These codes recognize the technical component and the various energy levels administered. It is important to code according to the level of service and the energy used.

When more than one treatment is performed on the same day, e.g., hyperfractionation, each treatment should be billed on a separate detail line.
Multiple treatment sessions on the same day are payable as long as there has been a distinct break in therapy services and the individual sessions are of the character usually furnished on different days. When billing for multiple treatments on the same day, the claim must document that there has been a distinct break between therapy. Statements such as "A.M. and P.M. treatments" suffice.

Radiation treatment delivery can be billed using a date range if the treatments are performed on consecutive days and the energy and level of service are the same, the total number being indicated in the CMS 1500 days or units field. If the dates of service are not consecutive or the energy or level of service is not the same, each date of service must be billed in a separate detail line.
The physician's documentation within the patient's medical record must support complexity of treatment and the specific energy levels reported to Medicare.

Two factors determine which treatment delivery code to choose:
the energy level used in treatment, in megavolts (MV); and
the complexity of treatment (defined as number of treatment sites, ports and devices).

These two selection criteria allow for the following matrix for determining which code to use:

Simple Treatment Delivery (77401, 77402, 77403, 77404, 77406)
single port
parallel ports
no devices
simple devices

Intermediate Treatment Delivery (77407, 77408, 77409, 77411)
2 separate areas treated
3 or more ports on a single area
multiple non-complex devices

Complex Treatment Delivery (77412, 77413, 77414, 77416)
3 or more areas treated
custom devices
rotational beam
compensator
electron beam
tangential ports
wedges

Tier Kilovoltage 5 MV 6-10 MV 11-19 MV 20 MV
Simple 77401 77402 77403 77404 77406
Intermediate 77401 77407 77408 77409 77411
Complex 77401 77412 77413 77414 77416

IMRT Treatment / Delivery 77418

Code(s) 77401 and 77418 may be quantity billed on the same line of the 1500 claim form.

G. Portal Verification Film(s) (CPT code 77417)

Use CPT code 77417 to report port verification films or electronically generated portal images. These images should agree with the original simulation films and dosimetry. Port film verification is a technical component only procedure and does not carry a professional physician component. No modifier is required for these services. The review and interpretation of port films by the physician, is considered part of the weekly clinical treatment management.
Although radiographs may be used in brachytherapy simulation, these images should not be reported as port-films.

Portal verification films should be reported as 1 charge per 5 fractions of therapy, per portal, one charge per port per week, with additional charges as needed as the patient's clinical status warrants. If at the end of a treatment course, three or four fractions remain, then one unit of portal verification will be reimbursed. If only one or two fractions remain, then no reimbursement will be made. This code (CPT 77417) may be used more than once per day per treatment course.

H. Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy. (CPT code: 77421)

Image Guided Radiation Therapy (IGRT) uses various imaging technologies to account for changes in the position of the intended target before or during treatment delivery. IGRT is used where patients have tumors located near or within critical structures and/or in tissue with inherent setup variation. Thus, although IGRT is a distinct service, it may be used and documented along with conformal treatment delivery (CPT 77402-77416) or IMRT treatment delivery (77418). Several different imaging modalities are used for IGRT. These include the use of kV and mV imaging via stereoscopic X-ray guidance, 2D or 3D ultrasound guidance, 3 D cone beam CT guidance, and 4 D localization and tracking of electromagnetic transponders. Some image guidance modalities require the implantation of fiducial markers; other image guidance modalities use external markers, the organ itself, or adjacent anatomic structures to reference location of the target.

I. Radiation Treatment Management (CPT codes 77427, 77431)
CPT code 77427 - Radiation treatment management, x5

The regulation reads:
Weekly Radiation Therapy Management (CPT 77427). Pay for a physician's weekly treatment management services under code 77427. Instruct billing entities to indicate on each claim the number of fractions for which payment is sought.

A weekly unit of treatment management is equal to five fractions or treatment sessions. A week for the purpose of making payments under these codes is comprised of five fractions regardless of the actual time period in which the services are furnished. It is not necessary that the radiation therapist personally examine the patient during each fraction for the weekly treatment management code to be payable.

Multiple fractions representing two or more treatment sessions furnished on the same day may be counted as long as there has been a distinct break in therapy sessions, and the fractions are of the character usually furnished on different days.
Code 77427 is also reported if there are three or four fractions beyond a multiple of five at the end of a course of treatment; one or two fractions beyond a multiple of five at the end of a course of treatment are not reported separately. The professional services furnished during treatment management typically consist of:

review of port films;
review of dosimetry, dose delivery, and treatment parameters;
review of patient treatment set-ups;
examination of patient for medical evaluation and management, (e.g., assessment of the patient's response to treatment, coordination of care and treatment, review of imaging and/or lab test results).

EXAMPLE:
18 fractions = 4 weekly services
62 fractions = 12 weekly services
8 fractions = 2 weekly services
6 fractions = 1 weekly service

If billings have occurred which indicate that the treatment course has ended (and, therefore, the number of residual fractions has been determined), but treatments resume, adjust your payments for the additional services consistent with the above policy.

EXAMPLE:
8 fractions = payment for 2 weeks
2 additional fractions are furnished by the same physician. No additional Medicare payment is made for the 2 additional fractions.

J. Radiation Therapy Management (CPT code 77431)

This CPT code is to be used only if a patient's entire treatment course consists of only one or two fractions. This code should not be used to bill for the remaining treatments at the end of a long course of therapy. The quantity billed should be one whether one or two fractions are used.

K. Special Treatment Procedures (CPT code 77470)
CPT code 77470 (Special radiation treatment) covers the additional physician effort and work required for the special procedures of:
hyperfractionation
total body irradiation
brachytherapy
hyperthermia
planned combination with chemotherapy; or
other combined modality therapy
stereotactic radiosurgery
intra-operative radiation therapy, and
hemibody irradiation
intracavitary cone use
radiation response modifiers
heavy particles (e.g. protons/neutrons)
3-D CRT
IMRT
any other special time consuming treatment plan.

This code is not intended for use when a patient has another ongoing medical diagnosis such as diabetes, C.O.P.D or hypertension.

It is considered an acceptable standard of practice for this code to be reported only once during a treatment course and may be billed with the weekly management codes.

For the remaining treatment course, a physician should use the appropriate weekly radiation therapy management codes (CPT codes 77427 and 77431) for the management of the patient.

If the treatment course is modified for any reason, the physician should use the appropriate CPT code for the simulation field setting and dosimetry. CPT code 77470 should not be used for this reason.

II. Intensity Modulated Radiation Therapy (IMRT)

Description:
Intensity Modulated Radiation Therapy (IMRT) is a new technology in radiation oncology that delivers radiation more precisely to the tumor while relatively sparing the surrounding normal tissues.
It is an advanced form of three-dimensional conformal radiation therapy (3D CRT) that allows for varying intensities of radiation to produce dose distribution that are more conformal than those possible with standard 3D CRT.

IMRT is a computer-based method of planning for, and delivery of, narrow, patient specific, spatially and temporally modulated beams of radiation to solid tumors within a patient. IMRT planning and delivery uses a new approach for obtaining the highly conformal dose distributions needed to irradiate complex targets positioned near, or invaginated by, sensitive normal tissues, thus improving the therapeutic ratios.

A. Treatment Planning
The computer based optimization process is referred to as 'inverse planning'. Inverse planning develops a dose distribution based on the input of specific dose constraints for the planned treatment volume (PTV) and nearby clinical structures, and is the beginning of the IMRT treatment planning process. The gross tumor volume (GTV), the PTV and surrounding normal tissues must be identified by a contouring procedure, and the optimization must sample the dose with a grid spacing of 1 centimeter or less.

IMRT treatment plans are geometrically more accurate and tailored to the target volumes than are conventional or three-dimensional radiation plans. The IMRT planning computer algorithm describes the necessary field sizes, gantry angles, and other beam characteristics needed to achieve the desired dose distribution. The essential feature of an IMRT plan is that it describes the means to deliver treatment utilizing non-uniform beam intensities.

Three-dimensional image acquisition by simulation (e.g., CT, MRI, PET or similar image fusion technology) is a prerequisite to IMRT treatment planning. The physician then outlines (contours) the visible abnormality seen on each slice of the image set. The three-dimensional summation of these contours defines the Gross Tumor Volume (GTV). The physician draws a margin around the GTV to generate a Clinical Target Volume (CTV) which encompasses the volume of tissue at risk for microscopic disease (not visible on imaging studies). To account for potential patient set-up variation or organ and patient motion, a final margin is then added to create what is termed the Planning Target Volume (PTV). The physician also contours nearby normal structures that potentially could be damaged by radiation ("organs at risk").

The physician must assign specific dose requirements for the PTV (minimum dose and dose homogeneity) and dose constraints for the organs at risk (maximum allowable doses). A treatment plan that satisfies these requirements and constraints should maximize the potential for disease control and minimize the risk of radiation injury to normal tissue.
Finally, the radiation physicist or a supervised dosimetrist calculates a complex multi-beam treatment plan that will deliver the prescription dose to the PTV and satisfy the normal tissue dose constraints. The radiation beam is, in effect, a collection of "beamlets," each with a different level of radiation intensity. The summation of these "beamlets" delivers the characteristic, highly conformal IMRT dose distribution. The PTV, therefore, receives a high dose of radiation while nearby organs receive significantly lower doses.

Prior to treatment delivery the physicist performs basic dose calculations on each of the modulated beams. These patient specific monitor unit computations verify through a second (independent of treatment planning) dose calculation method that the computer has correctly performed the treatment planning calculations. The calculated beams are then delivered either to a phantom or a dosimetry measuring device to confirm that the point dose and dose distribution are physically verifiable and that the intensity modulated beams are technically feasible.

Documentation of all aspects of the planning process is essential.

B. Treatment Delivery
IMRT treatment delivery can be accomplished through a variety of technologies. The most common approach utilizes a multi-leaf collimator (MLC) to modulate the intensity of the beam. Various forms of MLC technology include fixed gantry types such as static MLC (step and shoot) where the leaves do not move when the beam is on and dynamic MLC (sliding window) where they move during treatment. There are also moving gantry technologies including fan-beam therapy that uses a binary collimator to deliver slice-by-slice treatment and intensity modulated arc therapy, in which the gantry rotates while moving MLCs create non -uniform dose to the planning target volume during individual arc segments. A different technical solution for IMRT is to use a solid compensator with varying thickness filters to modulate the beam. The basic requirement for all forms of IMRT treatment delivery is that the technology must accurately produce the calculated dose distribution described by the IMRT plan.

IMRT uses non-uniform and customized fluence distributions in treatment delivery. Delivery and planning of IMRT may require the use of a multi-leaf collimator (MLC) with leaves that project to a nominal 1cm or less at the treatment unit isocenter. The MLC may be in a dynamic (DMLC) or segmented mode (SMLC) (mean segments per gantry position or 'steps' required to meet IMRT delivery is 5) to create the 3-dimensional, intensity-modulated dose distribution. These processes maybe called segmental, binary or step and shoot.

The use of a MLC to produce simple one-dimensional ramp intensity distributions is excluded because the inverse planning process is not expected to produce these intensity patterns.

Other planning and delivery methods include:
- Conformal Arc
- Intensity Modulated Arc
- Electronic forward planned compensator
- Inverse planned IMRT Solid Compensators

Note: There are also so called normal tissue compensators that do not produce IMRT. These devices are called wedges, compensators, etc. and do not modulate a beam into small "beamlets" as do IMRT. Do not bill for IMRT when it is not performed.

C. The exact planning and delivery method is not restricted as long as the particular technique chosen has the ability to model the highly modulated intensity patterns that result from the planning process described above and the planning/delivery method is FDA approved.

D. Patient immobilization is required for precision IMRT. A number of imaging techniques (e.g., ultrasound, kilovoltage or megavoltage cone beam CT scan, stereoscopic X-ray) may also be utilized to account for the daily motion of the PTV and more accurately deliver the treatment (Image Guided Radiation Therapy or IGRT). Changes in the location of the target within the body during a single fraction can arise from respiratory motion or other physiologic variances. To accommodate such changes the PTV may be drawn based upon published studies of organ motion or on dynamic imaging studies, or treatment delivery may be actively modulated by direct measures of motion during treatment.

IMRT delivery imposes a more stringent requirement than conventional radiation therapy in terms of accounting for patient position and organ motion.
Image Guided Radiation Therapy (IGRT) utilizes imaging technology to modify treatment delivery to account for changes in the position of the intended target. IGRT is used in conjunction with IMRT in patients whose tumors are located near or within critical structures and/or in tissue with inherent setup variation. Thus, although IGRT is a distinct service, it may be used and documented along with IMRT treatment delivery when necessary.

Methods that account for organ motion include but are not limited to:

1. use of published studies on organ movement when developing the PTV;
2. image guided adaptive radiotherapy (e.g. ultrasound guided or portal image guided setup with implanted fiducial markers, or 4D localization and tracking of electromagnetic transponders); and
3. respiratory gating of diaphragm movement for thoracic and upper abdominal sites.
(CPT codes: 76950, 77014, 77421, 0197T)
Indications and Limitations of Coverage:
The decision process for using IMRT requires an understanding of accepted practices that take into account the risks and benefits of such therapy compared to conventional treatment techniques. While IMRT technology may empirically offer advances over conventional or 3-Dimentional conformal radiation, a comprehensive understanding of all consequences is required before applying this technology.

IMRT is not a replacement therapy for conventional and 3D conformal radiation therapy methods.
IMRT is considered reasonable and necessary in instances where sparing the surrounding normal tissue is of added benefit and at least one of the following conditions is met:

• The target volume is in close proximity to critical structures that must be protected.
• The volume of interest must be covered with narrow margins to adequately protect immediately adjacent structures.
• An immediately adjacent area has been previously irradiated and abutting portals must be established with high precision.
• The target volume is concave or convex, and critical normal tissues are within or around that convexity or concavity.

• Dose escalation is planned to deliver radiation doses in excess of those commonly utilized for similar tumors with conventional treatment.

Indications
IMRT is indicated as a standard treatment option for:
1. Primary, metastatic or benign tumors of the central nervous system including the brain, brain stem and spinal cord;

2. Primary, metastatic tumors of the spine where the spinal cord tolerance may be exceeded with conventional treatment

3. Primary, metastatic, or benign lesions to the head and neck area including: Orbits, Sinuses, Skull base, Aero-digestive tract, Salivary glands;

4. Carcinoma of the prostate;

5. Selected cases of thoracic and abdominal malignancies;

6. Selected cases (i.e. not routine) of breast cancers with close proximity to critical structures;

7. Other pelvic and retroperitoneal tumors that meet the requirements for medical necessity; and

8. Reirradiation that meets the requirements for medical necessity.

Although IMRT is not indicated as the routine management for other cancers, IMRT is often reasonable and necessary treatment for other sites. There is no definitive list of "approved sites" nor is it possible to preclude some cancers solely on the basis of primary site of origin. The radiation oncologist must consider the five criteria detailed above (proximity to critical structures, narrow margins, previous radiation, target shape, and dose escalation requirement) and then determine if IMRT is indicated. For example, IMRT may be indicated in the treatment of lung cancers and intra-abdominal and pelvic malignancies where the effect of organ motion must be considered. In the case of breast cancer, while not routine, IMRT may be indicated when the tumor is in proximity to the heart. For all instances, the physician should document the indications for IMRT. It may be used as the primary/sole modality or as a boost to conventional therapy.

Coding Information

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

011x	Hospital Inpatient (Including Medicare Part A)
012x	Hospital Inpatient (Medicare Part B only)
013x	Hospital Outpatient
083x	Ambulatory Surgery Center

085x	Critical Access Hospital

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

033X	Radiology - Therapeutic and/or Chemotherapy Administration - General Classification

CPT/HCPCS Codes

Radiation Therapy
77261-77525 except CPT Code 77432 (Stereotactic Radiosurgery)

XX000	Not Applicable

IMRT

77301	INTENSITY MODULATED RADIOTHERAPY PLAN, INCLUDING DOSE-VOLUME HISTOGRAMS FOR TARGET AND CRITICAL STRUCTURE PARTIAL TOLERANCE SPECIFICATIONS
77338	MULTI-LEAF COLLIMATOR (MLC) DEVICE(S) FOR INTENSITY MODULATED RADIATION THERAPY (IMRT), DESIGN AND CONSTRUCTION PER IMRT PLAN
77418	INTENSITY MODULATED TREATMENT DELIVERY, SINGLE OR MULTIPLE FIELDS/ARCS, VIA NARROW SPATIALLY AND TEMPORALLY MODULATED BEAMS, BINARY, DYNAMIC MLC, PER TREATMENT SESSION
0073T	COMPENSATOR-BASED BEAM MODULATION TREATMENT DELIVERY OF INVERSE PLANNED TREATMENT USING 3 OR MORE HIGH RESOLUTION (MILLED OR CAST) COMPENSATOR CONVERGENT BEAM MODULATED FIELDS, PER TREATMENT SESSION
0197T	INTRA-FRACTION LOCALIZATION AND TRACKING OF TARGET OR PATIENT MOTION DURING DELIVERY OF RADIATION THERAPY (EG, 3D POSITIONAL TRACKING, GATING, 3D SURFACE TRACKING), EACH FRACTION OF TREATMENT

ICD-9 Codes that Support Medical Necessity

Note: ICD-9 codes must be coded to the highest level of specificity.
77261-77470 (except 77432)

140.0 - 239.9	MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - NEOPLASM OF UNSPECIFIED NATURE SITE UNSPECIFIED
242.00 - 242.01	TOXIC DIFFUSE GOITER WITHOUT THYROTOXIC CRISIS OR STORM - TOXIC DIFFUSE GOITER WITH THYROTOXIC CRISIS OR STORM
259.2	CARCINOID SYNDROME
277.89	OTHER SPECIFIED DISORDERS OF METABOLISM
289.4	HYPERSPLENISM
331.11	PICK'S DISEASE
332.0	PARALYSIS AGITANS
350.1	TRIGEMINAL NEURALGIA
350.8	OTHER SPECIFIED TRIGEMINAL NERVE DISORDERS
362.50	MACULAR DEGENERATION (SENILE) OF RETINA UNSPECIFIED
372.40 - 372.45	PTERYGIUM UNSPECIFIED - RECURRENT PTERYGIUM
378.12	MONOCULAR EXOTROPIA WITH A PATTERN
410.00 - 410.92	ACUTE MYOCARDIAL INFARCTION OF ANTEROLATERAL WALL EPISODE OF CARE UNSPECIFIED - ACUTE MYOCARDIAL INFARCTION OF UNSPECIFIED SITE SUBSEQUENT EPISODE OF CARE
411.1	INTERMEDIATE CORONARY SYNDROME
411.81	ACUTE CORONARY OCCLUSION WITHOUT MYOCARDIAL INFARCTION
413.0 - 413.9	ANGINA DECUBITUS - OTHER AND UNSPECIFIED ANGINA PECTORIS
414.01	CORONARY ATHEROSCLEROSIS OF NATIVE CORONARY ARTERY
527.2	SIALOADENITIS
701.4	KELOID SCAR
728.11	PROGRESSIVE MYOSITIS OSSIFICANS
728.13	POSTOPERATIVE HETEROTOPIC CALCIFICATION
733.90	DISORDER OF BONE AND CARTILAGE UNSPECIFIED
747.60 - 747.69	

	ANOMALY OF THE PERIPHERAL VASCULAR SYSTEM UNSPECIFIED SITE - ANOMALIES OF OTHER SPECIFIED SITES OF PERIPHERAL VASCULAR SYSTEM
747.81	CONGENITAL ANOMALIES OF CEREBROVASCULAR SYSTEM
789.2	SPLENOMEGALY
77301, 77418, 0073T (IMRT)	
140.0 - 198.89	MALIGNANT NEOPLASM OF UPPER LIP VERMILION BORDER - SECONDARY MALIGNANT NEOPLASM OF OTHER SPECIFIED SITES
201.00 - 201.98	HODGKIN'S PARAGRANULOMA UNSPECIFIED SITE - HODGKIN'S DISEASE UNSPECIFIED TYPE INVOLVING LYMPH NODES OF MULTIPLE SITES
202.00 - 202.08	NODULAR LYMPHOMA UNSPECIFIED SITE - NODULAR LYMPHOMA INVOLVING LYMPH NODES OF MULTIPLE SITES
202.80 - 202.88	OTHER MALIGNANT LYMPHOMAS UNSPECIFIED SITE - OTHER MALIGNANT LYMPHOMAS INVOLVING LYMPH NODES OF MULTIPLE SITES
202.90 - 202.98	OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE UNSPECIFIED SITE - OTHER AND UNSPECIFIED MALIGNANT NEOPLASMS OF LYMPHOID AND HISTIOCYTIC TISSUE INVOLVING LYMPH NODES OF MULTIPLE SITES
212.6	BENIGN NEOPLASM OF THYMUS
213.0 - 213.9	BENIGN NEOPLASM OF BONES OF SKULL AND FACE - BENIGN NEOPLASM OF BONE AND ARTICULAR CARTILAGE SITE UNSPECIFIED
225.0 - 225.9	BENIGN NEOPLASM OF BRAIN - BENIGN NEOPLASM OF NERVOUS SYSTEM PART UNSPECIFIED
227.3	BENIGN NEOPLASM OF PITUITARY GLAND AND CRANIOPHARYNGEAL DUCT
227.4	BENIGN NEOPLASM OF PINEAL GLAND
227.6	BENIGN NEOPLASM OF AORTIC BODY AND OTHER PARAGANGLIA
228.00 - 228.09	HEMANGIOMA OF UNSPECIFIED SITE - HEMANGIOMA OF OTHER SITES
237.0	NEOPLASM OF UNCERTAIN BEHAVIOR OF PITUITARY GLAND AND CRANIOPHARYNGEAL DUCT
336.9	UNSPECIFIED DISEASE OF SPINAL CORD
446.4	WEGENER'S GRANULOMATOSIS
459.2	COMPRESSION OF VEIN

747.81

CONGENITAL ANOMALIES OF CEREBROVASCULAR SYSTEM

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

General Information

Documentation Requirements

Documentation required with the claim:
1. For Radiation Dosimetry Calculations (CPT code 77300) when over six dosimetry calculations are reported, the documentation on the claim must support the medical necessity.
2. For Complex Daily Treatment Delivery (CPT codes 77401-77416) and Weekly
Radiation Therapy Management (CPT codes 77427) when billing for multiple treatments on the same day. The claim must document that there has been a distinct break between therapy. Statements such as "A.M. and P.M. treatments" suffice. The required information must be indicated in the appropriate Documentation Record for claims submitted electronically.
If paper claims are submitted, the required documentation must be on an attachment to the CMS - 1500 claim form. Claims submitted without this information will be denied as not medically necessary.

Documentation required in the patient's medical record: (Documentation must be available to Medicare upon request).

1. The patient's medical record must indicate the medical necessity of services for each date of service submitted on a claim, and documentation must be available to Medicare upon request.
2. Documentation in the medical record must include the planned course of therapy, type and delivery of treatment, level of clinical management involved and ongoing documentation of any changes in course of treatment.
3. A patient referral with diagnostic information and request for consultation for radiation oncology must be maintained in the patient's record and available to Medicare upon4.For Treatment Devices, Designs, and Construction (CPT codes 77332-77334).
Additional sets may be allowed only when documentation explains why new or additional devices are necessary. If such documentation is not present, or if the information simply describes the function of the devices, the service will be denied as not medically necessary. Examples of acceptable reasons for additional sets of devices are listed below:
The size of the lesion changes.

The patient is repositioned.
A different volume of interest is treated. (Identify each volume of interest).
A boost, change in size of the volume of interest, or coned down beam is used.

Documentation for IMRT in the medical record.
1. The reasonable and necessary requirements as outlined under the coverage and limitations sections of this policy and must be available to the Contractor for review upon request.

2. The prescription must define the goals and requirements of the treatment plan, including the specific dose constraints for the target(s) and nearby critical structures.

3. A statement by the treating physician documenting the special need for performing IMRT on the patient in question, rather than performing conventional or 3-dimensional treatment planning and delivery.

4. A signed IMRT inverse plan that meets prescribed dose constraints for the planning target volume (PTV) and surrounding normal tissue using either dynamic multi-leaf collimator (DMLC) or segmented multi-leaf collimator (SMLC) (average number of 'steps' required to meet IMRT delivery is 5 or more), or inverse planed IMRT solid compensators to achieve intensity modulation radiation delivery.

5. The target verification methodology must include the following:
a. Documentation of the clinical treatment volume (CTV) and the planning target volume (PTV).
b. Documentation of immobilization and patient positioning.
c. Means of dose verification and secondary means of verification.
d. Independent basic dose calculations of monitor units have been performed for each beam before the patient's first treatment.

6. Documentation of fluence distributions (re-computed and measured in a phantom or dosimetry measuring device) is required.

7. Identification of structures that traverse high-and low-dose regions created by respiration is indicated. Voluntary breath-holding alone is not a satisfactory solution for accounting for organ motion.

Appendices

Utilization Guidelines

Limitation of liability and refund requirements apply to denials for frequency and/or medical necessity. When the advance notice is given, the service (s) must be submitted with HCPCS modifier GA (advance notice has been given to the beneficiary).
Refer to the body of the policy for further utilization information.

OTHER COMMENTS
1. Definitions:

Bite block - A restraining device generally used in the oral cavity often attached to an outside source for patient stability.

Block - A device fabricated of an energy-absorbing material such as lead or Cerrobend (Wood's metal) to shape or delineate the treatment portal to match the configuration of the desired area and to shield or protect normal structures.

Bolus - A tissue equivalent material used to change the surface deposition of a radiation beam.

Compensator - An irregularly shaped beam-modifying device utilized to reconfigure the beam intensity to match irregular tissue contours.

Collimator - A beam shaping device attached to the head of the treatment machine to define the initial configuration (the length and width) of the treatment portal.

Dosimetry - The calculation of the radiation dose distribution within an area of clinical interest

Hyperfractionation - Radiation therapy delivered more than once per day.

Isodose - A plotting of lines or a series of lines following paths of the same dosage distribution within a treatment beam.

Mold - A patient restraining device usually constructed of plaster or thermosetting plastic that fits to the contour of the patient and restricts the motion of the patient during treatment.

Port, Portal - These words are synonymous and refer to the site, on the skin, where the radiation beam enters the body.

Portal Verification - Any means of verifying the placement and configuration of the treatment portal.

Simulation - The use of simulator, or other means, to determine the various treatment portal outlines and orientation to be used in the course of radiation therapy.

Simulator - A radiation generator operating in the diagnostic x-ray range. A simulator has the mechanical capability to orient a radiation beam toward a patient with parameters imitating that, which is proposed for therapy while affording direct x-ray fluoroscopic visualization and roentgenographic images of the area. This machine is not capable of delivering radiation therapy.

Stent - A splint-restraining device generally used in the oral cavity. The device is usually constructed of acrylic or some other dental material but may incorporate lead or other energy absorbing material to protect some portion of the cavity from direct dose deposition.

Stereotactic - A 3-dimensional technique of intersecting multiple portals creating complex interaction of the treatment beams and resulting isodose plans.

Teletherapy or External Beam Radiation - The delivery of a beam of electromagnetic energy from a treatment machine at some distance from the treatment area. External beam radiation is commonly delivered by a linear accelerator which can deliver photons (x-rays) or electrons to the targeted area.

Proton Beam Delivery (CPT codes 77520-77525)
Clinical use of proton beam therapy is relatively new and there are no facilities available within our jurisdiction at the present time.

Sources of Information and Basis for Decision

American College of Radiology (ACR) User's Guide.
American Medical Association's "Physician's Current Procedural Terminology CPT "
Board Certified Radiation Oncology physicians.

Carlos A. Perez, MD and Luther W. Bradley, MD, eds., Principles and Practice of Radiation Oncology, 3rd ed. (Philadelphia, Lippincott-Raven, 1998).
Policies of Carriers in Multiple States

IMRT
American College of Radiology (ACR) Radiation Oncology Carrier Advisory Committee (CAC) Network Model Policy on Intensity Modulated Radiation Therapy (IMRT) which includes the following references:
American College of Radiology (ACR)
American Society for Therapeutic Radiology and Oncology (ASTRO)
ACR/ASTRO Radiation Oncology Users Guide
CANCER, Principles & Practice of Oncology; by DeVita, Hellman, Rosenberg, Fifth Edition, Volume 2 Chapter 66, pp3090-3106; published by Lippincott-Raven
Fraass BA; Kessler ML; McShan DL; Marsh LH; Watson BA; Dusseau WJ; Eisbruch A; Sandler HM; Lichter AS: Optimization and clinical use of multisegment intensity-modulated radiation therapy for high-dose conformal therapy. Seminars Radiation Oncology 1999 Jan 9(1): 60-7
Intensity-Modulated Radiotherapy Collaborative Working Group. Intensity-Modulated Radiotherapy: Current Status and Issues of Interest. Int J Radiat Oncol Biol Phys 2001; 54(4): 880-914
Kuppersmith RB; GrecoSC; Teh BS et al: Intensity modulated radiotherapy: first results with this new technology on neoplasms of the head and neck. Ear Nose Throat J 1999 April;78(4):238-248
Nutting CM; Convery DJ; Cosgrove VP et al: Reduction of small and large bowel irradiation using an optimized intensity modulated pelvic radiotherapy technique in-patients with prostate cancer. Int J Radiat Oncol Biol Phys 2000; 48(3): 649-56
Pirzkall A, Carol M, Lohr F, et al. Comparison of Intensity Modulated Radiotherapy with Conventional Conformal Radiotherapy for Complex-Shaped Tumors. Int J Radiat Oncol Biol Phys 2000; 48(5): 1371-1380
Shu HG, Lee T, Vigneault E, et al. Toxicity Following High-Dose 3-Dimensional and Intensity-Modulated radiation Therapy for Clinically Localized Prostate Cancer. Urology 2001; 57(1) 102-107
Teh BS; Woo SY; Butler EB: Intensity modulated radiation therapy (IMRT): a new promising technology in radiation oncology. Oncologist 1999;4(6):433-42
Textbook of Radiation Oncology, by Leibel, Phillips, 1st Edition, Chapter 8 pp138-149, published by Saunders
Xia P, Fu K, Wong G, et al. Comparison of Treatment Plans Involving Intensity Modulated radiotherapy for Nasopharyngeal Carcinoma. Int J Radiat Oncol Biol Phys 2000; 48(2): 329-337
Zelefsky, MJ; Fuks, Z; et al: Clinical experiences with intensity modulated radiation therapy (IMRT) in prostate cancer. Radiother Oncol 2000 Jun;55 (3)241-249

2009 (American Society for Radiation Oncology (ASTRO))

General IMRT References
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Chao KSC, ed, Apisarnthanarax S, asst ed, Ozyigit G, asst ed. Practical Essentials of Intensity Modulated Radiation Therapy, 2nd Edition. Philadelphia, PA: Lippincott Williams & Wilkins; 2005.
American Medical Association. Current Procedural Terminology (CPT)™ 2007. Chicago, IL: American Medical Association Publishing; 2007.
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Advisory Committee Meeting Notes

Meeting Date:
Wisconsin: 01/16/2009
Illinois: 01/28/2009
Michigan: 01/07/2009
Minnesota: 01/22/2009
Iowa 02/12/2009
Missouri 02/12/2009
Kansas 02/12/2009
Nebraska 02/12/2009
This policy does not reflect the sole opinion of the contractor or the Contractor Medical Director(s). Although the final decision rests with the contractor, this policy was developed in cooperation with the Carrier Advisory Committee(s), which include representatives of various medical specialty societies.

This policy was presented at an open meeting on: 12/17/2008

* - An asterisk indicates a revision to that section of the policy.

Start Date of Comment Period

02/12/2009

End Date of Comment Period

03/29/2009

Start Date of Notice Period

12/01/2009

Revision History Number

3

Revision History Explanation

07/25/2009 Updates completed for 8/16/09 effective date.

No change to LCD

08/08/2009 - This policy was updated by the ICD-9 2009-2010 Annual Update.

11/15/2009 - CPT/HCPCS code 77338 was added to the code range 77261 - 77431 in group 1

12/01/2009, Added CPT code 77338 effective 01/01/2010

04/19/2010—In accordance with Section 911 of the Medicare Modernization Act of 2003, the states of American Somoa, California, Guam, Hawaii, Nevada and Northern Mariana Islands were removed from this LCD because claims processing for those states are transitioning from FI ContractorWisconsin Physician Services (WPS - 52280) to MAC Part A Contractor Palmetto.

8/1/2010 - The description for Bill Type Code 11 was changed
8/1/2010 - The description for Bill Type Code 12 was changed
8/1/2010 - The description for Bill Type Code 13 was changed
8/1/2010 - The description for Bill Type Code 83 was changed
8/1/2010 - The description for Bill Type Code 85 was changed

8/1/2010 - The description for Revenue code 0330 was changed
8/1/2010 - The description for Revenue code 0331 was changed
8/1/2010 - The description for Revenue code 0332 was changed
8/1/2010 - The description for Revenue code 0333 was changed
8/1/2010 - The description for Revenue code 0335 was changed
8/1/2010 - The description for Revenue code 0339 was changed

09/06/2010 - This policy was updated by the ICD-9 2010-2011 Annual Update.

10/01/2010 - Add 237.73, 237.79 (Included in range 140.0-239.9)

10/18/2010 - In accordance with Section 911 of the Medicare Modernization Act of 2003, the states of Colorado, New Mexico, Oklahoma and Texas were removed from this LCD because claims processing for those states are transitioning from FI Wisconsin Physicians Service (52280) to MAC Part A Trailblazer (04901).

Reason for Change

Last Reviewed On Date

10/01/2010

Related Documents

This LCD has no Related Documents.

LCD Attachments

Coding and Billing Guidelines (PDF - 40,505 bytes)

All Versions

Updated on 10/06/2010 with effective dates 10/18/2010 - N/A

Updated on 10/04/2010 with effective dates 10/01/2010 - 10/17/2010

Updated on 10/04/2010 with effective dates 10/01/2010 - N/A

Updated on 08/01/2010 with effective dates 04/19/2010 - 09/30/2010

Updated on 08/01/2010 with effective dates 04/19/2010 - N/A

Updated on 04/14/2010 with effective dates 04/19/2010 - N/A

Updated on 03/05/2010 with effective dates 01/01/2010 - 04/18/2010

Updated on 08/19/2009 with effective dates 08/16/2009 - 12/31/2009

Updated on 07/28/2009 with effective dates 08/16/2009 - N/A

Updated on 07/25/2009 with effective dates 08/16/2009 - N/A

Updated on 07/25/2009 with effective dates 08/16/2009 - N/A

Updated on 07/16/2009 with effective dates 08/16/2009 - N/A

DETACH CERTIFICATE

DETACH CERTIFICATE

State of Illinois
IEMA Division of Nuclear Safety
Accreditation in Medical Radiation Technology

This is to certify that: Kathleen Peters

Accreditation No.: 500490311

has met the requirements for: Conditional Accreditation

in the Catg. of: Radiation Therapy - Valid Only at Valley Cancer Center @ Spring Valley

Expires: 07/31/2012

9689

101972039

(Use original card for verification)

PEEL CARD HERE

Kathleen Peters
870 Windsor Pl
Varna, IL 61375-9559

Questions / Address Changes - Contact Agency at 217/785-9913

IMPORTANT INFORMATION ON REVERSE SIDE OF CARD

EXHIBIT

tabbies

F

Court Name: US District Court SDO
Division: 1
Receipt Number: 100CIN010175
Cashier ID: langs
Transaction Date: 11/29/2010
Payer Name: JACOBS KLEINMAN SEIBEL MCNALLY

CIVIL FILING FEE
For: JACOBS KLEINMAN SEIBEL MCNALLY
Case/Party: D-OHS-1-10-CV-000833-001
Amount: $350.00

CHECK
Remitter: JACOBS KLEINMAN SEIBEL MCNALLY
Check/Money Order Num: 22699
Amt Tendered: $350.00

Total Due: $350.00
Total Tendered: $350.00
Change Amt: $0.00

A fee of $45.00 will be assessed on
all returned checks.